

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO 16-MD-2738 (FLW) (LHG)

IN RE JOHNSON & JOHNSON
POWDER PRODUCTS MARKETING,
SALES PRACTICES. : DAUBERT HEARING
----- : JULY 30, 2019
----- : VOLUME 7
----- :

CLARKSON S. FISHER UNITED STATES COURTHOUSE
402 EAST STATE STREET, TRENTON, NJ 08608

B E F O R E: THE HONORABLE FREDA L. WOLFSON, USDJ

A P P E A R A N C E S:

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On behalf of the Plaintiffs Steering Committee

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(Continued.)

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On Behalf of Defendant Personal Care Products Council

M O R N I N G S E S S I O N

3 (In open court.)

4 THE DEPUTY CLERK: All rise.

5 THE COURT: Thank you. Good morning.

6 Everyone may be seated.

7 MS. O'DELL: Good morning, your Honor.

8 Your Honor, may it please the Court, we would
9 like to call to the stand Dr. Daniel Clarke-Pearson.

11 **DANIEL CLARKE-PEARSON**, called as a witness on behalf
12 of the Plaintiffs, having been first duly sworn,
13 testified as follows:

15 DIRECT EXAMINATION

16 BY MS. O'DELL:

17 | Q. Good morning, Dr. Clarke-Pearson.

18 A. Good morning.

19 Q. Would you share with the Court your field of
20 expertise, your professional background, and some of
21 your professional activities?

22 A. My field of expertise is gynecologic oncology.

23 I went to Harvard College and received a

24 Bachelor's degree in biology; went to medical school
25 at Case Western Reserve University in Cleveland, Ohio

1520

1 and then undertook my residency training in obstetrics
2 and gynecology; and then a fellowship for three years
3 in gynecologic oncology at Duke University Medical
4 Center in Durham, North Carolina

5 Following completion of the fellowship, I
6 joined the Duke faculty as an assistant professor; and
7 aside from two years as director of gynecologic
8 oncology and gynecology at the University of Illinois,
9 I returned to Duke and then was on the faculty for
10 another 18 years, being promoted to Professor and then
11 the Distinguished Professor with an endowed chair.
12 During that time I was the director of a fellowship in
13 gynecologic oncology training fellows to become
14 gynecologic oncologists as well.

15 Q. Doctor, have you devoted your career to academic
16 medicine?

17 A. Yes. I have never been in private practice
18 throughout my career.

19 Q. Why did you choose to do that?

20 A. I think for the three main reasons that we're in
21 academic medicine, of course, to provide excellent
22 clinical care to our patients; to teach the next
23 generation of students, residents, fellows, and junior
24 faculty to become excellent providers of women's
25 healthcare; and then promote the knowledge base in our

1 field by conducting research. So that has attracted
2 me to be able to do all those things. It has been
3 very enjoyable, and I feel like I have been productive
4 and hopefully moved the field forward.

5 Q. You have been asked here today to talk about the
6 issue of talcum powder and ovarian cancer. As part of
7 your duties as an academic physician, do you regularly
8 teach fellows? Is that part of your normal
9 occupational activities?

10 A. That's what I like to do and that's my
11 obligation as well to teach fellows, yes.

12 Q. Are fellows required to master curriculum in
13 order to become Board Certified?

14 A. Yes, the American Board of Obstetrics and
15 Gynecology certifies fellows to become Board
16 Certified. But there is a curriculum and expectations
17 before they can take their boards to meet certain
18 criteria and to have a certain level of knowledge
19 above and beyond what a general obstetrician and
20 gynecologist would have.

21 So the board publishes annually a bulletin
22 that sets out the criteria or the knowledge elements
23 that need to be part of the fellowship training
24 program. As fellowship director for 18 years, that
25 was my obligation, to make sure that training was

1 provided to those fellows.

2 Q. Does that training include information that
3 talcum powder is a risk factor for ovarian cancer?

4 A. Yes, it does. It talks about all risk factors
5 associated with gynecologic cancers, including talcum
6 powder.

7 Q. In addition to your involvement as an academic
8 physician, have you also devoted a lot of time and
9 energy to professional organizations in the field of
10 obstetrics and gynecology in general and also to
11 gynecologic oncology?

12 A. Certainly. I feel a professional obligation to
13 get outside of my ivory tower and participate in
14 national organizations. So my primary national
15 organization for gynecologic oncology is the Society
16 of Gynecologic Oncology, of which I have been a member
17 since I was Board Certified. In 2010 through '11, I
18 was the president of the Society of Gynecologic
19 Oncology, leading that group.

20 I have also been very involved with the
21 American College of Obstetrics and Gynecology, a
22 number of committees. I won't list them all.
23 Probably most important in my mind is Chairing the
24 Gynecologic Management Committee, which is a committee
25 that writes committee opinions guiding clinical

1 practice for obstetricians and gynecologists and the
2 breadth of gynecology, not just GYN oncology.

3 Currently I'm a member of the Society of
4 Gynecologic Oncology's Ethics Committee.

5 And up until last month, I was the President
6 of the Council of Universal Chairs in Obstetrics and
7 Gynecology. I'm now the past president?

8 Q. Have you also published in the area of
9 gynecologic cancers and also ovarian cancer?

10 A. Yes. I've published a little over 250
11 peer-reviewed publications as part of my academic
12 interest and commitment. Most of those papers are in
13 the field of gynecologic oncology, and some have dealt
14 with ovarian cancer, in particular, clinical trials
15 describing advances in the treatment of ovarian
16 cancer.

17 Q. We've heard a lot about ovarian cancer,
18 epithelial ovarian cancer. I don't think at this
19 point in the hearing we've had someone really describe
20 ovarian cancer. Would you take a few minutes and
21 describe ovarian cancer, the incidence, how it occurs,
22 the clinical course, the symptoms involved, and just
23 give us a general overview?

24 A. Sure. I think there is an illustration. I
25 think before we get into the illustration, I would

1 frame this by saying that ovarian cancer in the big
2 world of cancer is a relatively rare cancer.
3 Fortunately, I have been focused on a limited number
4 of cancers in my career. Ovarian cancer probably
5 occupies about 50 percent of the patients I take care
6 of. One can argue, why is that because endometrial
7 cancer is a much more common uterine cancer. But in
8 2005 I chose not to develop a skillset doing robotic
9 surgery, and so I'm not doing surgery for endometrial
10 cancer.

11 THE COURT: Let me interrupt you a second. I
12 know you said you are not in private practice and
13 you're associated with the medical school, but you do
14 see patients?

15 THE WITNESS: Yes.

16 THE COURT: That was not clear from your
17 testimony. I thought you were essentially teaching. I
18 didn't actually know you actually saw patients.

19 THE WITNESS: Right.

20 THE COURT: Thank you for clarifying that.

21 BY MS. O'DELL:

22 Q. How much of your time over the course of your
23 career would be involved in treating patients and
24 teaching other physicians to treat patients?

25 A. While I was at Duke as fellowship director and

1 director of the division I was clinically active
2 80 percent of my waking hours, I suppose. After going
3 to the University of North Carolina in 2005 to become
4 Chair of the department, I cut my clinical practice
5 about 50 percent. So I still see patients and operate
6 2 1/2 days a week. I hope that clarifies.

7 THE COURT: Thank you. I'm sorry to
8 interrupt.

9 Q. You may continue.

10 A. With regard to ovarian cancer which occupies
11 about half of my clinical time now, ovarian cancer, I
12 started to say it's rare. It accounts for about
13 22,000 women a year developing ovarian cancer.
14 Unfortunately, it's a disease there is no way to
15 screen for it that we have been able to find yet, and
16 the symptoms are vague.

17 So the diagnosis is not made until most
18 patients have the disease spread well beyond the
19 ovaries, as this illustration shows cancer growing on
20 the surface of the ovaries. 75 percent of the time
21 patients that we take care of are not just my patients
22 but nationally the cancer spreads throughout the
23 entire abdominal cavity, much like dandelion seeds in
24 the wind will float around and land on surfaces,
25 attach and start growing. But those symptoms are very

1 vague. Many patients have some vague GI symptoms,
2 bloating, abdominal pressure, decreased appetite.
3 Nothing that's very specific. That's why it makes it
4 difficult to diagnose this cancer very early. So
5 75 percent of the time it's spread well beyond the
6 ovary, sometimes in the Stage IV, into the liver and
7 into the lung, and pleural space with fluid.

8 The treatment for ovarian cancer by and large
9 is surgery initially to remove as much of the cancer
10 as we can, what we call debulking, taking out the bulk
11 of the cancer. That surgery can sometimes be very
12 extensive, removing colon, small bowel, spleen, liver
13 resections, lymph nodes.

14 THE COURT: Can you back up from the mike a
15 little bit. Close enough that we hear you but not too
16 close.

17 Q. Go ahead.

18 A. It's extensive surgery. And then as quickly as
19 we can get the patient over surgery, initiate
20 chemotherapy. The usual chemotherapy program
21 stretches over about six months. Hopefully, the
22 patient appears to be in remission at that time,
23 although the majority of patients, even if they appear
24 to be in remission, will recur most of the time within
25 two years where we will restart, may do some more

1 surgery, but many times reinitiate chemotherapy,
2 working our way through different chemotherapy
3 regimens and experimental therapies.

4 The patients altogether have a survival at
5 five years of somewhere between 30 and 50 percent of
6 these patients that have advanced ovarian cancer I'm
7 describing. So most will end up dying of their
8 ovarian cancer.

9 Q. What are the histologic subtypes of ovarian
10 cancer?

11 A. There are three general categories of ovarian
12 cancer. The one we are talking about today is what's
13 called epithelial ovarian cancer which is nicely
14 illustrated in this drawing. It's a cancer that
15 starts from the surface of the ovary, what we call the
16 epithelium, a membrane, if you will. It expands and
17 grows out through that surface, and we see this cancer
18 here, but then it quickly sheds off of the ovary and
19 spreads throughout the abdomen as I described. That's
20 called epithelial ovarian cancer. That makes up the
21 great majority of ovarian cancers.

22 There are some subtypes I'll talk about in a
23 minute.

24 The second type of ovarian cancer is what's
25 called the germ cell ovarian cancer, which is not what

1 we are talking about today. It's a cancer that arises
2 in young women. The average age is about 19, where
3 these patients with epithelial ovarian cancer the
4 average age is somewhere 55 to 60. So germ cell
5 cancers are a different ovarian cancer altogether.

6 The third cancer category that we talked about
7 are called sex cord stromal tumors of the ovary, and,
8 again, we're not really talking about that with regard
9 to talcum powder.

10 Going back to epithelial cancers, there are
11 subtypes. The most common is a serous histology, what
12 they see under the microscope. There is also an
13 endometrioid histology, a clear cell histology, and a
14 mucinous.

15 So those are all lumped into the category of
16 epithelial ovarian cancer.

17 Q. Is epithelial ovarian cancer a disease of one
18 organ or is it multiple organs?

19 A. They talk about ovarian cancer, but I think in
20 the last decade it's become clear that ovarian cancer
21 is really a disease that can arise either from the
22 ovary or the fallopian tube. And you can see in this
23 illustration, the fallopian tube, which is right here,
24 would lead into the uterus, which is over here, can
25 develop malignant cells that will fall onto the ovary

1 and grow.

2 They are indistinguishable, one from the
3 other, so fallopian tube cancer and epithelial ovarian
4 cancers under the microscope look the same, and they
5 can spread through what's called the peritoneum, the
6 abdominal cavity. In some cases, we'll classify these
7 as primary peritoneal cancer, but they are really the
8 same cancer.

9 In most cases, in clinical trials, when we are
10 doing research with chemotherapy regimens, we are
11 treating these cancers with the same drugs. They look
12 the same under the microscope, they act the same and
13 respond the same to the chemotherapy regimen. So I
14 believe they're all the same. We lump them together
15 and call them epithelial ovarian cancer.

16 Q. Did you formulate opinions regarding the
17 relationship between talcum powder products, Johnson's
18 Baby Powder and Shower To Shower, and epithelial
19 ovarian cancer?

20 A. I did.

21 Q. Would you please just describe for the Court
22 your opinions, summarize your opinions.

23 A. I think there is a slide that might illustrate
24 that, embellish what I have been saying, sort of
25 bulleted points.

1 So after doing extensive research of the
2 literature, I believe that genital application of
3 talcum powder, such as Johnson & Johnson's Baby Powder
4 and Shower To Shower, increases the risk of epithelial
5 ovarian cancer in all women and can cause epithelial
6 ovarian cancer in some women.

7 Looking particularly at the epidemiologic
8 studies in their totality, there are many studies --
9 and it's only fair to look at them in their totality
10 -- the data shows really consistent statistically
11 significant increased risks of developing epithelial
12 ovarian cancer after application of talcum powder to
13 the perineum. Overall, the risk based on these
14 epidemiologic studies is increased somewhere between
15 20 and 60 percent when compared to women who don't use
16 talcum powder on their perineum.

17 The next point would be the mechanism is one
18 of migration or ascension of the talcum powder from
19 the perineum from the vulva through the vagina,
20 cervix, uterus, and out the fallopian tube to rest on
21 the ovary and peritoneum as the route of exposure.
22 Inhalation is also a plausible mechanism for exposure.

23 The mechanism by which talcum powder causes
24 ovarian cancer to occur is one of inflammation, and by
25 that I mean chronic inflammation that results in

1 oxidative stress and then mutations of the ovarian
2 cells become malignant. We know from animal and
3 experimental studies and in humans that talcum powder
4 elicits an inflammatory response.

5 Finally, Johnson's Baby Powder and Shower To
6 Shower contain other carcinogens, such as asbestos,
7 fibrous talc, platy talc, heavy metals, and fragrance
8 chemicals that also contribute to the carcinogenicity
9 of the product.

10 Q. Dr. Clarke-Pearson, you have also described in
11 summary fashion up to this point your methodology.
12 Would you take a few minutes and go through it in more
13 detail, what process you undertook to reach your
14 opinions in this case.

15 A. Certainly. I was asked to consider whether I
16 think talcum powder might cause ovarian cancer. So
17 I've started out doing a literature search, like I
18 would to try to answer any other medical clinical
19 question, and started looking at the epidemiologic
20 literature, which is fairly extensive, and goes
21 through several decades. Those include case-control
22 studies, cohort studies, pooled studies, and
23 meta-analyses. So lots of studies to review.

24 I also asked myself the question and reviewed
25 the literature as to what the mechanism might be that

1 talcum powder can cause ovarian cancer. I think my
2 steps in identifying that mechanism included the
3 migration: How did the talcum powder get to the
4 ovary, and then the inflammatory -- chronic
5 inflammatory response that it caused. There is
6 literature that we'll talk about that supports this
7 mechanism.

8 Then the use of talcum powder as a risk
9 factor. The epidemiologic data shows what the
10 significant risk is. Then I applied a Bradford Hill
11 causation analysis. It's much similar to what I do in
12 medicine with an evidence-based medicine decision
13 analysis to come to the conclusion what's best to
14 treat a patient.

15 Q. Let's turn to your review of the epidemiologic
16 literature. Did you consider the case-control and
17 cohort studies?

18 A. Yes, I tried to say I reviewed everything I
19 could possibly find, yes.

20 Q. On the screen you will see a forest plot.
21 Please describe for the Court your analysis of this
22 data.

23 A. I'm sure you have seen this before.

24 THE COURT: Many times.

25 A. A forest plot shows relative risks and

1 confidence intervals. The forest plot here includes
2 all of these studies that are case-control studies,
3 and these studies on the forest plot are actually
4 three studies that are reported. I think the key to
5 me is the relative risk on this forest plot aside from
6 maybe just a couple of examples like this one are all
7 to the right of 1, which means the relative risk is
8 increased over baseline.

9 Nearly all of these case-control studies and
10 nearly all of these cohort studies the relative risk
11 is above 1. So it's an increased relative risk. Many
12 of these studies also show statistically significant
13 increased risk.

14 Q. Let's take a closer look at the top of the list
15 of studies. One of the most recent case-control
16 studies is the Schildkraut study. Did you review and
17 rely on the Schildkraut study?

18 A. I reviewed all of the studies, Schildkraut being
19 the most recent case-control I'm aware of. It was
20 well done and thoughtful and addressed many issues
21 that were not addressed in earlier studies.

22 MS. O'DELL: Could you pull up general
23 causation opposition Exhibit 8, which is the
24 Schildkraut study.

25 Q. Dr. Clarke-Pearson, what were the results of

1 this study?

2 A. This is a study of specifically African-American
3 women from many regions throughout the United States.
4 I believe it was 11. In their analysis, they
5 concluded that genital powder was associated with the
6 increased risk of epithelial ovarian cancer, the
7 44 percent increased risk that was statistically
8 significant.

9 In addition, and this study compared to many
10 other case-control studies, the investigators
11 attempted and did look at issues with regard to
12 dose-response, and found that there was association of
13 dose-response, both in terms of frequency and
14 duration, a number of lifetime applications that was
15 statistically significant associated with the
16 occurrence of ovarian cancer.

17 So in their conclusions of these
18 African-American women, body powder was significantly
19 associated with epithelial ovarian cancer risk, a
20 44 percent increase.

21 Q. Did these researchers comment on the mechanism
22 by which talcum powder can cause ovarian cancer?

23 A. Yes. Again, in their conclusions, in their
24 discussion, they felt it was consistent with localized
25 chronic inflammation due to particulates that travel

1 through direct transvaginal route, so the migration or
2 ascension of talcum powder to the ovaries and
3 fallopian tubes, and that there is a dose-response
4 observed as well.

5 Q. Is this description consistent with localized
6 chronic inflammation in the ovary due to particulates
7 that travel to a direct transvaginal route, does that
8 support your opinion regarding the mechanism in this
9 case?

10 A. This plus other information and literature
11 supports the concept of chronic inflammation causing
12 cancer and the transport or migration, yes.

13 Q. You said you considered all the studies. Did
14 that include the meta-analyses that have been done on
15 the literature in this case?

16 A. Yes, I reviewed all those.

17 Q. Let's go back to the PowerPoint. Is this a
18 chart of the results of the meta-analyses?

19 A. Yes. All of these on the top are meta-analysis,
20 and this is a pooled analysis by Terry. But the
21 meta-analyses that you are asking about show basically
22 a very consistent increased relative risk on this
23 forest plot; and, in fact, all of these studies show a
24 statistically significant increased risk of ovarian
25 cancer. None of these confidence intervals overlap 1.

1 So these are all statistically significant with an
2 increased risk.

3 Q. In your review, what weight did you place on
4 meta-analysis?

5 A. A meta-analysis is one where the authors have
6 looked at, basically brought together the existing
7 literature, many case-control studies and cohort
8 studies, and analyzed them all together, rather than
9 one by one. And so I placed a lot more weight on that
10 when you combine all of the data.

11 Some studies are stronger and some are weaker
12 in those case-control studies. But giving weight to
13 all those studies in these meta-analysis, I think it
14 is important to be fair and honest rather than cherry
15 picking really good studies or really poor studies.
16 They take in everything in the literature and analyze
17 them and come up with this forest plot, if you will,
18 for each one of these.

19 The oldest study was in 1992 with only six
20 studies in it. But over time, we added more and more
21 information; and as we added more and more information
22 to the number of studies, the statistical significance
23 and relative risk stays very coherent, and the
24 confidence intervals are actually tighter because we
25 have more patients in them. There is more certainty

1 in all of these, but they are all statistically
2 significant.

3 Q. You noted the most recent studies -- strike
4 that.

5 The most recent meta-analyses have all the
6 studies considered in them, one of those being Berge.

7 Doctor, why don't we take a closer look at the
8 Berge study and have you walk us through the results
9 of that analysis.

10 A. This is a study of the risk of ovarian cancer.
11 So their conclusions, after doing a meta-analysis of
12 all these studies, show that the relative risk of
13 developing ovarian cancer associated with the genital
14 use of talcum powder was 1.22 or 22 percent increased
15 risk. The confidence interval of 1.13 to 1.3 is
16 statistically significant.

17 They also looked at the relative risk in the
18 case-control study specifically, and that risk was
19 26 percent, and for the cohort studies it was .02. So
20 not statistically significant, but the relative risk
21 is increased. But when they analyzed it based on one
22 specific cell type, the serous type, which is the most
23 common type of epithelial ovarian cancer, it was also
24 increased in these cohort studies to 24 percent.

25 Q. Was that statistically significant?

1 A. Yes, it was statistically significant.

2 Q. Did they also consider dose-response in this
3 particular study?

4 A. This is one of the issues that comes up in many
5 of these cohort studies, and also the case-control
6 studies don't really address dose-response. But other
7 studies that do address dose-response, there was a
8 trend to increased risk, the increased dose, the
9 patient receives whether it is by frequency or
10 duration of application.

11 Q. Did you also consider the Penninkilampi study?

12 A. I did. I was just talking about dose-response
13 for a moment. This is, again, from the Berge study.
14 So 12 of the studies had information that would be
15 helpful in terms of understanding duration and
16 dose-response, and that relative risk was 16 percent
17 increased risk statistically significant.

18 And in seven of those studies we were able to
19 analyze frequency of utilization of talcum powder in
20 the genital tract, and, again, statistically
21 significant with about a 5 percent increased risk for
22 patients who use talcum powder more frequently.

23 Q. Did you consider the Penninkilampi study?

24 A. Yes. That was another one of the more recent
25 meta-analysis that included 27, I believe, studies.

1 Q. Would you share with the Court your analysis of
2 the Penninkilampi study?

3 A. Certainly.

4 Once again, I think this meta-analysis is
5 fairly consistent with the Berge study, that the
6 overall risk or risk is increased statistically to
7 31 percent; and in this study, again, they made an
8 attempt to look at dose and found that there was an
9 apparent breakpoint in patients that had more or less
10 than 3600 lifetime applications of talcum powder.
11 Those with more than 3600 had an overall risk of 42
12 percent that was statistically significant.

13 Q. Did they do a subgroup analysis of the cohort
14 studies?

15 A. They did and again found an association with
16 talcum powder use and serous ovarian cancer. So that
17 one specific subtype, which is the most common
18 epithelial ovarian cancer, the relative risk there was
19 25 percent.

20 Q. What percentage of epithelial ovarian cancers
21 are the serous subtype?

22 A. The serous type make up about 80 percent of all
23 the epithelial ovarian cancers. I mentioned
24 endometrioid, clear cell and mucinous which make up,
25 all together, about 20 percent.

1540

1 Q. What were the conclusions of the authors in this
2 study?

3 A. Well, they felt there was consistent association
4 between the use of perineal talc and ovarian cancer.

5 Q. In addition to the results of the study, did the
6 researchers also comment on the mechanism by which
7 talcum powder could cause ovarian cancer?

8 A. The mechanism that Penninkilampi and his
9 co-authors felt was the cause of talcum powder causing
10 ovarian cancer was, again, this chronic inflammatory
11 response which predisposed to development of ovarian
12 cancer.

13 To be more specific, that includes cell injury
14 by the talcum powder that results in oxidative stress,
15 local increase in inflammatory mediators, such as
16 cytokines and prostaglandins that lead to a mutation
17 in that normal ovarian cell, epithelial cell to become
18 carcinogenic where that cell becomes malignant.

19 THE COURT: Let me ask you a question. Both
20 the Berge and Penninkilampi studies both came out in
21 2018?

22 THE WITNESS: Yes.

23 THE COURT: The numbers are slightly
24 different. What were the different studies they
25 looked at? Are there differences in the studies?

1 THE WITNESS: Slightly different studies.

2 THE COURT: Tell me what they were.

3 THE WITNESS: There were cohort studies that
4 they chose to use one, Gertig in one case, and Gates
5 in the other, I believe. Gertig and Gates were both
6 from the Nurses' Health Study. It was the same study,
7 the cohort study, but the Gertig and Gates analyzed it
8 slightly differently in one. I forget which one.
9 They assigned patients if they had never used talc or
10 used it once a week or less, they lumped those
11 patients together as if they didn't use talc, whereas
12 the other one included separated low dose from never
13 use. I think these two authors Berge and
14 Penninkilampi -- again, they don't explain in the
15 paper why they chose to choose one or the other.

16 THE COURT: Was that the only difference in
17 the studies they reviewed while the case studies were
18 the same?

19 THE WITNESS: Yes.

20 BY MS. O'DELL:

21 Q. Did the researchers in Penninkilampi conclude
22 that there was a causal relationship between talc and
23 ovarian cancer?

24 A. Yes. The statistical significance is there and
25 the mechanism they are describing on this slide was

1 chronic inflammation.

2 Q. Let's transition for a moment,

3 Dr. Clarke-Pearson, and have you walk us through your
4 analysis to reach a causation opinion in this case.

5 What was your methodology for that? Remind us.

6 A. My methodology was a Bradford Hill analysis.

7 Q. Walk us through your Bradford Hill analysis.

8 A. The Court has seen these factors in Bradford
9 Hill before. But using the strength of association
10 and consistency in my analysis, I felt there was
11 overwhelming support in the epidemiologic literature
12 that talcum powder statistically increased a woman's
13 risk of developing epithelial ovarian cancer by about
14 30 percent, and every meta-analysis actually showed
15 similar increases. So it was consistent.

16 In terms of specificity, the epidemiologic
17 studies appears that this is specific for ovarian
18 cancer, not other cancers, vaginal cancer, uterine
19 cancer, and it satisfies the consideration of
20 specificity.

21 Regarding temporality, in my opinion we have
22 demonstrated and it's been shown that talcum powder
23 exposure before the onset of ovarian cancer, so the
24 timing is such and that for most malignancies there is
25 a clear latency period sometimes decades from the

1 exposure of the talcum powder in this case to the
2 development of obvious ovarian cancers. So it takes
3 time to have that malignant transformation. That's
4 the timeline that it takes. It doesn't happen in a
5 day or two. So the temporality I believe is
6 satisfied.

7 The biologic gradient and dose-response,
8 again, some of these studies don't address
9 dose-response, but the ones that do demonstrate that
10 there is a dose-response both in terms of frequency of
11 use and duration of use. There are several references
12 there.

13 Going on to biological plausibility, I think
14 it's clear talcum powder ascends from the perineum
15 through the vagina, cervix, and uterus to the ovary.
16 It is known as an agent to cause inflammation, and the
17 inflammatory reaction by talcum powder on the tube and
18 surface of the ovary results in genetic mutations that
19 I mentioned before and then cancer. So I think that's
20 the mechanism by which talcum powder causes ovarian
21 cancer.

22 The coherence issue, I think the epidemiologic
23 data, in vitro data that I know the Court's heard
24 previously and experimental studies and in vivo
25 research are consistent in explaining the pathogenesis

1 of epithelial ovarian cancer.

2 THE COURT: Having reviewed the in vivo
3 research, and that's mostly what's there, the timing,
4 since you have talked about the long latency period,
5 and these studies talk about 24 hours, 48, 72 hours,
6 explain that to me, if you can.

7 THE WITNESS: I'm not a laboratory researcher,
8 those that are doing the in vitro research. But you
9 are right. They are taking a snapshot of the exposure
10 of talcum powder to cell lines, and those studies have
11 demonstrated an inflammatory response. They haven't
12 gone on to say, well, we have seen malignant
13 transformation.

14 THE COURT: All of them stop short of that
15 because none of them can do that.

16 THE WITNESS: I'm not sure of one that shows
17 actual malignant transformation. I think that would
18 take time in a laboratory, that latency period you are
19 talking about and I'm talking about.

20 THE COURT: So the most that it can show is,
21 it showed some changes in inflammatory response?

22 THE WITNESS: Yes, and mutations, and we see
23 in one study single nucleotide polymorphisms. So
24 these are mutations that are happening, and that's the
25 next step toward malignant mutations.

1 So SNPs are mutations. And while there are
2 some really significant mutations that are associated
3 with ovarian cancer, like BRCA 1 and 2, a combination
4 of a number of SNPs can add up to increase in the risk
5 of ovarian cancer, and there are a number of studies
6 that are showing that, not in vitro but in vivo, in
7 human studies.

8 THE COURT: Let me ask you: During your
9 Bradford Hill analysis, for instance, when you got to
10 coherence you say satisfied. Obviously, on biological
11 plausibility, you said "critical factor."

12 Now, you are looking at the in vitro and in
13 vivo. Is that because you also think that is a less
14 of a showing to you to convince you?

15 THE WITNESS: Would you repeat that again?

16 THE COURT: In looking at the in vitro and
17 in vivo research, you say they are consistent; we know
18 they don't get to the end point of showing
19 transformation. So in your consideration of the
20 factors, how much weight do you give to that factor?

21 THE WITNESS: I think the evidence in my view
22 is the chronic inflammation is well established in
23 both in vivo and in vitro studies, and that chronic
24 inflammation then -- and we'll talk about it in a
25 little bit more -- I think now, today, actually,

1 probably a decade ago was well-established as the
2 causation for many cancers, not all, but many. So
3 there is chronic inflammation that is well established
4 in my opinion and in the in vivo and in vitro studies
5 is that step towards truly invasive cancer.

6 THE COURT: You can continue.

7 BY MS. O'DELL:

8 Q. Would you continue, Doctor.

9 A. With regard to experimentation, clearly there is
10 no randomized trials that would be unethical to do
11 that. So if you want to talk about experimentation,
12 we just talked about in vitro experiments that are
13 showing this chronic inflammation, genetic mutations
14 that are happening.

15 There are some sort of natural experiments, if
16 you will, that are not randomized but evidence that
17 tubal ligation reduces the risk of ovarian cancer that
18 we believe is protecting that ovary from something
19 ascending through the tube from the ovary, talcum
20 powder, endometrial cells from the lining in the
21 uterus. So some of those are experiments that show
22 some protective benefit.

23 Likewise, use of birth control pills reduces
24 the risk of ovarian cancer by suppressing ovulation.
25 We'll talk about ovulation in a minute as a risk

1 factor.

2 And then analogy. I think the most
3 straightforward in my mind is the medical literature
4 with regard to minerals causing cancer, including
5 ovarian cancer, but asbestos and lung cancer being the
6 most obvious analogy to talcum powder and ovarian
7 cancer.

8 Q. Dr. Clarke-Pearson, you just mentioned the term
9 "risk factor." How do you as an academic physician
10 define risk factor?

11 A. So risk factor is a factor that increases the
12 risk of a malignancy -- in this case ovarian cancer --
13 and statistically increases the risk, and then in some
14 patients goes on to cause that cancer. I think we
15 also feel there should be a logical mechanism by which
16 that risk factor is working. I think for ovarian
17 cancer risk factors, we have established the mechanism
18 in all risk factors for ovarian cancer.

19 Q. What is the mechanism you are referring to?

20 A. There are several mechanisms. I think the end
21 result is mutation of the normal cell to become a
22 malignant cell. We have been talking about chronic
23 inflammation. A good number of ovarian cancers are
24 caused by inflammation. There are other things
25 besides talcum powder that cause inflammation, but

1 there is also the genetic mutation.

2 So the woman that has a BRCA 1 or 2 mutation
3 has that mutation. She's inherited that mutation and
4 is at a significant increased risk. So that's a risk
5 factor not every woman with those mutations develops
6 ovarian cancer, but they develop ovarian cancer in a
7 much higher frequency than if they didn't have that
8 mutation.

9 This is a list of risk factors I put together.
10 There might be another two. The most significant is
11 the BRCA 1 and 2 mutations increase a risk from -- the
12 average woman in America today, has a risk of about
13 1.3 percent of developing ovarian cancer in her
14 lifetime; women with BRCA 1 mutations have about a 30
15 to 40 percent increased risk. So a substantial
16 increased risk.

17 Other risk factors on this table, family
18 history of breast or ovarian cancer increases risk.
19 So understanding that, it is important. Again, I
20 think that's genetics -- and it may be other BRCA 3 or
21 4 that we haven't identified yet, are being passed in
22 that family, and these SNPs that might increase the
23 risk to 5 or 6 percent.

24 Q. Which of these risk factors are associated with
25 inflammation?

1 A. I think starting with lifetime risk and on down
2 through -- lifetime ovulation, retrograde
3 menstruation, blood flowing from the uterus out
4 through the fallopian tubes. Talcum powder products
5 and others are probably better illustrated on this
6 slide. So I can walk through the different sorts of
7 reasons there is inflammation that then leads to
8 oxidative stress and gene mutations and cancer, and
9 all of these risk factors on this slide.

10 Retrograde menstruation means when the patient
11 has their menstrual period, the menstruation, the
12 menstrual fluid which has endometrial cells in it,
13 instead of coming out through the cervix and vagina,
14 some of it goes backwards, retrograde, out the
15 fallopian tubes, into the pelvis, landing on pelvic
16 surfaces and the ovary.

17 When it lands there, especially on the ovary,
18 it's a foreign body and it causes chronic
19 inflammation. And in some patients -- well, we know
20 patients with endometriosis have an increased risk of
21 developing clear cell cancer of the ovary, which is an
22 epithelial ovarian cancer.

23 Obesity is an epidemic in the United States,
24 and it is a systemic inflammatory response.

25 So associated with many cancers -- breast

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1 cancer, colon cancer, but also statistically
2 associated with ovarian cancer, and I think we
3 understand or believe that's secondary to this chronic
4 inflammatory response the body has to being obese.
5 I'm not enough of a scientist to tell you why that
6 happens, but it goes along with obesity.

7 Ovulation and frequent ovulation or incessant
8 ovulation have been identified as a risk factor for
9 ovarian cancer for decades, and I think the
10 explanation is one, again, of inflammation and
11 healing.

12 I've got a little video that might show the
13 Court what actually happens in ovulation.

14 Q. Why don't you walk us through this.

15 A. So this is going to be an ovary. At the time of
16 ovulation, in mid-cycle, a follicle has been
17 developing from the last menstrual period up until
18 about midway through that menstrual cycle. Usually
19 midway the patient ovulates. So that follicle
20 contains follicular fluid, and so it's -- you can see
21 it.

22 It's like a little cyst or maybe a blister
23 that ultimately -- and so the fallopian tube is over
24 here. It's not very clear, but it's right beside it,
25 and the idea here in normal reproduction is that egg

1 is going to come out of this follicle, bursts out
2 through there. If all things go well, the fallopian
3 tube captures this fertilization and the patient is
4 pregnant with the embryo in the uterus. But we're
5 just talking about ovulation right now.

6 So this ovulatory event, this event of
7 ovulation -- go ahead and run the video some more.
8 This follicle expands and ultimately, however, you
9 want to say it explodes and that ovum comes flying
10 out. This is the ovum in this follicular fluid. It's
11 going to burst forth.

12 Now, the issue is what's happening here is
13 whether it's a blister that's ruptured or a pimple
14 that's ruptured, but this healing that has to happen.
15 That's the follicular fluid bursting out, and the egg
16 or ovum coming out. But this is where the problem
17 lies.

18 This ovarian epithelium has to heal, and the
19 healing process requires growth and stimulation.
20 Growth factors come in here, cytokines come in, there
21 is an inflammatory response, and then hopefully it
22 heals. But in some cases this increases the risk of
23 epithelial ovarian cancer by ovulating.

24 The evidence on the other side of the coin is
25 if you stop ovulation by using birth control pills, by

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1 pregnancy, by breast feeding, which stops ovulation in
2 most cases, women that have any of those factors have
3 a reduced risk of developing ovarian cancer. So
4 stopping ovulation reduces the risk of ovarian cancer.
5 So that's the inflammatory and repair process that
6 results in ovarian cancer, the epithelium in some
7 women.

8 Other things that cause chronic inflammation,
9 polycystic ovarian syndrome is a condition that has
10 many cysts on the ovary. Patients are infertile and
11 obese usually as a chronic inflammatory response to
12 that ovary.

13 Pelvic inflammatory disease, which is usually
14 caused by gonorrhea and Chlamydia is successfully
15 treated with antibiotics. So that patient that's
16 successfully treated doesn't have a chronic
17 inflammatory response. But some women will have
18 chronic inflammatory disease and the epidemiology
19 shows those patients with chronic pelvic inflammatory
20 disease have a higher risk statistically of developing
21 ovarian cancer.

22 And then talcum powder and asbestos exposure
23 that we're talking about today, the evidence shows
24 chronic inflammatory response to the ovary and
25 peritoneum which then leads to this oxidative stress

1 production of cytokines and then gene mutations, and
2 those mutations result in cancer.

3 Q. Very quickly. Are there protective factors?
4 You mentioned one and that is reduced ovulation.
5 Would pregnancy reduce ovulation, that would be a
6 protective factor?

7 A. Yes, protective factors would be use of birth
8 control pills. Use of oral contraceptives for five
9 years in a woman's life reduces the risk by about 40
10 to 50 percent. We should be using birth control pills
11 to prevent ovarian cancer. It is not labeled that way
12 but it could be. Unfortunately, you think about it
13 just as a birth control. But it could be used as a
14 preventive, and I use it in some patients who are high
15 risk.

16 Pregnancy, a woman doesn't ovulate during
17 those nine months of pregnancy. Women that breast
18 feed in general do not ovulate. So those reduce the
19 risk. I mentioned previously tubal ligation and
20 hysterectomy also reduce the risk of ovarian cancer.

21 Q. You have talcum powder and asbestos exposure on
22 your slide as an inflammatory risk factor for ovarian
23 cancer. Has it been reported in the literature that
24 talcum powder is a risk factor for ovarian cancer?

25 A. Yes, widely reported in the recent literature,

1 yes.

2 Q. Let me ask you, Doctor, before we talk about
3 some of those specific references, just to explain
4 something to us about: Is it your opinion talcum
5 powder causes an inflammatory response?

6 A. Yes.

7 Q. You showed the video of ovulation and the
8 injury, if you will, to the epithelial surface of the
9 ovary during the normal cycle. Can you explain to us
10 how those work together, how the presence of talcum
11 powder in that setting could intensify an inflammatory
12 response?

13 A. Certainly.

14 Well, in some parts of the body, such as the
15 lung, there is a clearance mechanism in the lung with
16 mucous and cilia that gets particles out of the lung.
17 In the ovary there is no clearance mechanism to get
18 things out. So if talcum powder were present at the
19 time of ovulation and it became embedded in that
20 healing process, so that talc particle is now embedded
21 in the ovarian epithelium, the body can't get rid of
22 it. That is a chronic irritant and causes chronic
23 inflammation, and there are studies that have shown
24 talc within not just on the surface of the ovary, but
25 in ovarian tissue.

1 Q. Let's transition now to some of the publications
2 that recognize talcum powder as a risk factor for
3 ovarian cancer. An article by Hunn and Rodriguez. Is
4 Hunn and Rodriguez the next publication?

5 A. This is a review article on ovarian cancer
6 etiology, what causes ovarian cancer, risk factors and
7 the epidemiology.

8 Q. Do they include a table of the risk factors for
9 ovarian cancer?

10 A. Quickly going to the table, they list risk
11 factors here that I listed most on the other slide to
12 simplify things. One of the risk factors they
13 identify is inflammation, and of the inflammation
14 endometriosis causing inflammation, pelvic
15 inflammatory disease, but on this list they also
16 include perineal talc exposure as an inflammatory risk
17 factor for epithelial ovarian cancer.

18 Q. Also there is the Mallen reference. Are those
19 four of the references that you reviewed and relied on
20 in sort of evaluating whether talcum powder is a risk
21 factor?

22 A. All these address talcum powder and identify it
23 as a risk factor.

24 Q. Tell us about the Mallen article, please.

25 A. This is a relatively recent paper and it's a

1 review paper. It's basically addressing the risk
2 factors.

3 Q. Do they include a table of the risk factors for
4 ovarian cancer?

5 A. In this study the authors attempted to segregate
6 these epithelial ovarian cancer cell types from --
7 separating serous from high grade serous, low grade
8 serous, endometrioid and clear cell subtypes of
9 epithelial cancer, and then they assign risk factors
10 for each of these subtypes of epithelial ovarian
11 cancer.

12 In all serous you can see I highlighted it.
13 Genital powder use is a lifestyle risk factor. So
14 something a woman would choose in her lifestyle to use
15 or not. It's also associated with endometrioid and
16 clear cell carcinomas. It's not clear that high grade
17 serous and low grade serous are associated but all
18 serous are associated with genital powder use.

19 The problem with some of this analysis is low
20 grade serous is a very small number fraction of all
21 serous cancers.

22 Q. Did you also consider the book chapter from
23 Cancer Prevention and Screening by -- edited by Eeles,
24 and did they list talcum powder as a lifestyle risk
25 factor?

1 A. Yes. They sort of break it down into different
2 risk factors. In the category of lifestyle there is
3 other lifestyle issues that women and men can choose,
4 whether it's alcohol use, obesity, cigarette smoking,
5 but talc use is also listed as a lifestyle risk
6 factor, and talc in the genital area has consistently
7 been shown to increase the risk of ovarian cancer and
8 is not recommended by these authors of this textbook.

9 Q. Lastly, Dr. Clarke-Pearson, did you consider the
10 Vitonis publication that assessed risk factors for
11 ovarian cancer?

12 A. I did. This is from 2011. So it's not brand
13 new.

14 In this study the authors were going beyond
15 just listing risk factors to adding weight to risk
16 factors and trying to create a formula, if you will,
17 using these eight risk factors to create a scoring
18 system. They tried to evaluate a specific patient who
19 might have not none of these risk factors or might
20 have one or might have eight.

21 And so of the eight risk factors they included
22 Jewish ethnicity, goes along with BRCA mutations, less
23 than one year of oral contraceptive use, I won't read
24 all of this, and then they added or included talc use
25 as one of the eight risk factors that would fit into

1 this formula to come up with a score.

2 Q. Dr. Clarke-Pearson, why is it significant that
3 talcum powder is being reported as a risk factor for
4 ovarian cancer in the literature?

5 A. I'm sorry.

6 Q. Why is it significant that talcum powder is
7 being reported as a risk factor for epithelial ovarian
8 cancer in the literature?

9 A. Well, again, I think it's a lifestyle choice.
10 It is not something a woman needs to do. There is
11 just no medical indication to use talcum powder on the
12 perineum. If it is recognized as a risk factor and a
13 woman can choose not to use talcum powder and reduce
14 her risk of ovarian cancer, then why not in my
15 perpective.

16 Q. Dr. Clarke-Pearson, you shared with us this
17 morning that you've practiced in the field of
18 gynecology for, I think, probably 40 years. Is that a
19 fair assumption?

20 A. I think that's fair.

21 Q. Would it also be fair to say that you have done
22 thousands of pelvic exams over your career?

23 A. Yes, I probably do 25 every Thursday.

24 Q. We heard a lot in this litigation about
25 migration, and, specifically, there have been

1 arguments made by the defendants that it's impossible
2 for talcum powder to migrate from the perineum to the
3 fallopian tubes and ovaries. Is that true? What's
4 your opinion? And please describe for us your reason
5 for reaching your opinion.

6 A. We'll get to these articles in a second that
7 show migration from the vagina to the ovary. I think
8 that's quite clear.

9 It seems to me that the argument that's being
10 put up is something from the perineum from the vulva
11 from the outside skin can't get into the vagina.
12 There is no lid or door -- I suppose if a young girl
13 had an imperfect hymen, that might be the only way
14 there is a barrier. Otherwise, the vulva and vagina
15 are in continuity with each other and then in
16 continuity with the cervix, uterus, fallopian tubes.

17 So it's just well accepted in the gynecology
18 community, obstetrics and gynecology community that
19 the conduit or the connection between the outside
20 world and the vagina and cervix and uterus are there.
21 It's quite obvious. There is no sphincter.

22 We think about the rectum. There is an anal
23 sphincter we can hold things in with. There is no
24 sphincter in the vagina. There is a sphincter on the
25 urethra and we can hold in urine and we can hold in

1 poop with our rectal sphincter, but there is no
2 sphincter on the vagina. So it's just open, and
3 depending upon other factors a woman that has a baby
4 vaginally, and the vagina opens to 10 centimeters to
5 allow a baby to come out, that is just in continuity
6 back and forth. So I think the gynecology community
7 believes and recognizes that this is a direct
8 connection.

9 Q. I know you've reviewed the literature, some of
10 which is on the screen.

11 In addition to your training and experience
12 and your knowledge as an academic physician who has
13 practiced for more than 40 years, what is some of the
14 literature that supports your opinion that talcum
15 powder can migrate?

16 A. We can spend a lot or little time. These are
17 all human experiments where the first one, carbon
18 particles, were put in the vagina, radioactive
19 particles were put in the vagina, glove powder just on
20 pelvic examination came off the gloves. It was not
21 intentionally put in the vagina. It was just glove
22 powder.

23 In those three papers, migration from the
24 vagina to the fallopian tube and ovary occurred within
25 24 hours. Then you could say: Well, wait a minute.

1 This is a particle. It doesn't have any motility to
2 it. It's just a carbon particle or radioactive
3 microsphere. How did it get there?

4 So this paper on uterine peristaltic pump,
5 it's been well demonstrated with ultrasound that the
6 uterus actually has -- the uterus is contracting in
7 labor to push the baby out. But the uterus during the
8 menstrual cycle contracts and has a retrograde so it
9 pumps upward, if you will, and that pumping mechanism
10 increases in the early part of the menstrual cycle
11 until the mid-cycle, right before the follicle comes
12 out, before the egg comes out of the follicle. That
13 gets the maximum pumping mechanism in a retrograde
14 fashion which pumps things up and works toward getting
15 that egg into the fallopian tube.

16 It also can pump sperm, and that's intense. I
17 think biologically, the pump is pulling sperm. If we
18 just put sperm in the cervix and believe it is going
19 to get to the tubes in a very short period of time,
20 the sperm is motile, but it doesn't move that fast.
21 The experiments with this peristaltic pump shows that
22 sperm moves much faster than what would be expected up
23 into the fallopian tube to hopefully achieve pregnancy
24 because of this peristaltic pump.

25 So there is this pump that's going backward,

1 and it is a demonstration of putting microspheres on
2 the cervix at different points in the menstrual cycle.
3 In mid-cycle, when you want to biologically optimize
4 pregnancy, that pump is bringing sperm up into the
5 uterus and fallopian tubes.

6 So whether it's the pump bringing up sperm or
7 bringing up talcum powder or other things, it pumps or
8 pulls that up. It's not just a passive flow, because
9 there's been arguments I've read where: Well, there
10 is a flow out of the uterus, menstrual period, and
11 that sort of thing, and that's true. But this
12 peristaltic pump in mid-cycle, when there is not a
13 menstrual period, is actually going the other
14 direction, pulling things up into the fallopian tubes.

15 Q. Has the presence of talcum powder in the ovary
16 been evidenced by studies of pathology?

17 A. Yes.

18 Q. Let me ask another question, just about the
19 normal activities of a woman. Does a woman's daily
20 activities affect particles or environmental agents
21 entering the vagina?

22 A. I would think so. Let's just talk about sexual
23 intercourse for a second. If there is talcum powder
24 on the vulva and the woman is having vaginal
25 intercourse, I would think it's very plausible, it's

1 hard to believe that it wouldn't happen that the
2 talcum powder would be introduced into the vagina, and
3 all these studies support the ascension migration all
4 the way up to the fallopian tube.

5 Using a tampon, riding a bike or a horse, I
6 think many of those daily activities would result in
7 making the vagina accessible to any product that's on
8 the vulva.

9 Q. Dr. Clarke-Pearson, do you understand that the
10 FDA has written that it's indisputable that talcum
11 powder can migrate to the ovary? Have you heard that?

12 A. I read that in one of their letters, yes.

13 Q. Is that in agreement with your opinion?

14 A. I think that's what I have been saying. I'm in
15 agreement with the FDA on that topic.

16 Q. Let's transition from migration and talk just
17 briefly about inhalation. Did you consider inhalation
18 as another route of exposure to the ovary?

19 A. Yes. I think it's possible.

20 THE COURT: Possible or probable?

21 THE WITNESS: I think it's plausible. It's
22 less likely than the ascension through the vagina and
23 the genital application. I think it's much stronger.

24 THE COURT: But you would use the word
25 "plausible"?

1 THE WITNESS: Yes.

2 BY MS. O'DELL:

3 Q. Doctor, I skipped this slide regarding the
4 pathology studies. Is there any particular study you
5 want to comment on?

6 A. I think I sort of, in answering one of your
7 questions, said, yes, that talc has been found to be
8 embodied in the ovaries. There are two studies up
9 there, '71 and '96, and talc has been found in pelvic
10 lymph nodes which had to, in my mind, ascend through
11 the vagina and into the lymphatics and out from the
12 pelvic organs out into the lymphatics on the pelvic
13 side wall, and then asbestos has been found in the
14 ovaries.

15 Q. Doctor, I'm going to skip a few slides here.

16 THE COURT: Are we finished on inhalation?

17 MS. O'DELL: Do you have any questions about
18 inhalation, your Honor, other than the one you asked?

19 THE COURT: He just said it's plausible. I
20 want to understand why and what you think the
21 mechanism is?

22 THE WITNESS: There is evidence that talcum
23 powder that's inhaled can migrate to the ovary through
24 either lymphatics or through the bloodstream. It's
25 much less likely, but I think the mechanism is there.

1 This is an IARC statement from, I believe, 2012 that
2 says that inhalation and dermal contact through
3 perineal application of talcum powders are primary
4 routes of exposure.

5 THE COURT: What do you think that inhalation
6 was based on? That comment in there, what did they
7 rely on?

8 THE WITNESS: I think they are relying on --
9 I'm not sure. I would be speculating.

10 THE COURT: Thank you.

11 BY MS. O'DELL:

12 Q. Doctor, you said earlier that talcum powder
13 causes inflammation. You mentioned in vitro studies.
14 I think you mentioned animal studies as well.

15 Would you just walk through some of the
16 evidence you are aware of in humans that talcum powder
17 causes inflammation.

18 A. Sure. The inflammation question is one that I
19 think are probably two good examples. Early in my
20 training in the early 1970s, talcum powder was on
21 surgical gloves, and we were told, instructed to, once
22 we had our gloves on, and the talcum powder made the
23 gloves go on easier, to wash the outside of our
24 gloves.

25 So we would go to a basin and wash the gloves

1 because it was found that talcum powder that lands
2 inside the pelvis or abdomen causes inflammation,
3 which results in scarring, adhesions, which we didn't
4 want to cause especially in women we are operating on
5 where we don't want to cause adhesions in their
6 fallopian tubes and cause infertility, and could cause
7 granulomas, which are an inflammatory response trying
8 to wall off talcum granules. So it's pretty good
9 evidence in my opinion it causes inflammation.

10 The other part that's quite obvious and used
11 medically even today is what's called pleurodesis
12 where talcum powder is stuck through or a needle of
13 some sort into the pleural space between the lung and
14 chest wall with the intention of scarring the lung to
15 the chest wall.

16 This is in situations in my patients with
17 ovarian cancer that have fluid which is called pleural
18 effusion in their chests, the space between the lung
19 and the chest wall. It's filled with fluid being
20 caused by the cancer. The patient then develops
21 respiratory distress, and it's very uncomfortable. So
22 we put in a chest tube, drain that fluid to let the
23 lung expand, and then put talc in and scar the two
24 together to prevent that fluid from reaccumulating.
25 The mechanism by which that scarring happens is

1 inflammation.

2 Q. Dr. Clarke-Pearson, is it generally-accepted
3 that inflammation causes cancer?

4 A. Chronic inflammation causes cancer.

5 Q. And as part of your review in this case, did you
6 consider the Balkwill article that describes that
7 inflammatory process? This is Exhibit 98.

8 So Balkwill, this was a review paper?

9 A. Right. This was a review paper in Lancet, which
10 is a very prominent New England Journal, and Lancet
11 are probably the two most prominent medical
12 publications.

13 In the Lancet this review article is talking
14 about inflammation and cancer, and it's not just
15 ovarian cancer. It's talking about the evidence that
16 inflammation, chronic inflammation causes a variety of
17 different cancers.

18 Q. Doctor, just briefly, would you walk us through
19 what is being depicted in terms of inflammation
20 causing cancer.

21 A. This is an illustration from that review article
22 that's sort of in a cartoon diagram, describes what's
23 happening, starting over here on the left with normal
24 cells. They could be ovarian epithelium, that this
25 chronic inflammation causes tissue damage and chronic

1 infection, if it's pelvic inflammatory disease or
2 chronic inflammation impacts these cells.

3 These cells react. They try to heal. That's
4 the normal process. Cytokines and chemokines are
5 created, but this process of healing doesn't always
6 occur because there is chronic inflammation, and so
7 cells then become mutated. And we start working our
8 way down this process.

9 This is sort of a gradual progression of
10 malignancy going from left to right. So the DNA
11 damage that occurs by this chronic inflammation,
12 growth stimulation. The cancer cells that are now
13 developing don't have the same apoptosis mechanism.
14 So programmed cell death is apoptosis, which is what
15 normal cells go through, but cancer cells don't as
16 much, and so they continue to grow instead of go
17 through that cycle of programmed cell death.

18 Angiogenesis is cell death. For that early
19 cancer to really take hold and grow, it needs to have
20 a blood supply, and these malignant cells and the
21 products that they are making, growth factors,
22 vascular endothelial growth factors, one product being
23 made by these cells stimulates angiogenesis, growth of
24 blood vessels into the tumor, and also these cells are
25 producing products that are hiding those cancer cells

1 from the immune system, so the immune system isn't
2 recognizing them as abnormal.

3 So all of this allows the promotion and
4 development of a malignancy. But it all starts back
5 here at this inflammatory process.

6 Q. Is this process you just described also true
7 about epithelial ovarian cancer? There have been some
8 arguments made by defense experts that inflammation
9 does not cause epithelial ovarian cancer. Is that
10 true?

11 A. I disagree with that. And we're talking about
12 talc today predominantly, but I showed you on the
13 slide other things that are causing chronic
14 inflammation, whether it's chronic pelvic inflammatory
15 disease, endometriosis, obesity.

16 So chronic inflammation is what I think we
17 believe, it's not just my belief, causes ovarian
18 cancer in many circumstances aside from those that
19 have gene mutations.

20 Q. Is there a figure from the Shan and Liu
21 publication? Did you review this publication?

22 A. Yes, I reviewed this as another review article.
23 It specifically talks about ovarian cancer.

24 MS. O'DELL: If we go to the figure.

25 Q. Doctor, briefly we talked about cancer

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1 generally; and if you could become more specific in
2 your discussion about how inflammation causes ovarian
3 cancer.

4 A. I think this is the same representation but in a
5 diagram form of ovulation, that rupture of the ovarian
6 capsule and epithelium and healing process that
7 happens here. All those cytokines and chemokines and
8 prostaglandins that are produced in that healing
9 process are all active right here on this ovarian
10 surface.

11 If we could blow this up.

12 This is a diagram representation. These are
13 epithelial cells on the surface of the ovary, and
14 below that is the stroma or fibroblast, fibrous tissue
15 that these cytokines, chemokines, and prostaglandins,
16 growth factors that are out here after ovulation, and
17 then other things that are causing inflammation, like
18 talcum powder, impact this ovarian epithelium and
19 stimulate the premalignant growth of these epithelial
20 cells.

21 Q. Doctor, let's transition just for a moment and
22 specifically talk about the components of talcum
23 powder. What's your understanding of the components
24 of talcum powder?

25 A. Certainly.

1 The majority, as I understand it, is platy
2 talc, but it also includes fibrous talc, asbestos
3 particles, heavy metals and chemicals that make up the
4 fragrance of talcum powders.

5 Q. Is asbestos, fibrous talc and heavy metals, do
6 you understand them to be known carcinogens?

7 A. Known carcinogens, yes.

8 Q. Do they work through an inflammatory mechanism?

9 A. Yes.

10 Q. Is that generally accepted that that's the mode
11 by which they induce carcinogenesis?

12 A. Yes.

13 Q. Does the presence of those components in talcum
14 powder contribute to your opinion in this case?

15 A. Yes, it does, but I think the epidemiology just
16 takes talcum powder as a whole product. So what's in
17 it is hard to identify what specifically is the
18 carcinogen. Maybe it's all there. I don't think
19 anybody has been able to dissect that out.

20 Q. Did they provide evidence of a biologically
21 plausible mechanism by which talcum powder can cause
22 ovarian cancer?

23 A. Yes. A number of carcinogens can cause and do
24 cause ovarian cancer.

25 Q. Finally, Doctor, is it your opinion that the

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1 genital use of talcum powder causes epithelial ovarian
2 cancer?

3 A. Yes, it's my opinion.

4 Q. Do you hold that opinion to a reasonable degree
5 of medical certainty?

6 A. Yes, I do.

7 MS. O'DELL: I have nothing further, Doctor.
8 Thank you so much.

9 THE COURT: We'll take our break now and then
10 start the cross.

11 You can step down, Doctor.

12 THE DEPUTY CLERK: All rise.

13 (Recess.)

14 (Continued on the next page.)

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1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4 **DANIEL CLARKE-PEARSON**, resumed.

5

6 CROSS-EXAMINATION

7 BY MS. BROWN:

8 Q. Good morning, Dr. Clarke-Pearson.

9 A. Good morning.

10 Q. Doctor, to your absolute credit, you have spent
11 the last 40 years of your professional life treating
12 women with suspected or diagnosed gynecologic cancers.
13 Correct?

14 A. Yes.

15 Q. And that would include ovarian cancer? Correct?

16 A. Yes.

17 Q. You have published hundreds of articles in the
18 field of gynecologic oncology?

19 A. About 250.

20 Q. You have been a leader in some of the
21 gynecologic oncology organizations you spoke to us
22 about, SGO and SCOG. Correct?

23 A. Yes.

24 Q. For 40 years you have researched and taught and
25 practiced in the field of gynecologic oncology. Fair?

1 A. Yes.

2 Q. But in over 40 years of practice,
3 Dr. Clarke-Pearson, you have never told a patient that
4 talcum powder caused her ovarian cancer. True?

5 A. That's probably true. I can't recall every
6 single patient I talked to. I rarely had the question
7 asked of me.

8 MS. BROWN: Permission to read, your Honor.

9 THE COURT: YES.

10 Q. Can we look at B-10. Dr. Clarke-Pearson, this
11 is from your deposition on February 4th, 2019. You
12 were asked at line 11:

13 "QUESTION: Have you ever told a patient that
14 talcum powder caused her ovarian cancer?

15 "ANSWER: No."

16 A. Okay.

17 Q. Dr. Clarke-Pearson, in your 40 years of
18 practice, you have never recommended increased
19 screening or monitoring for ovarian cancer based on a
20 patient's prior use of talcum powder products. True?

21 A. That's true, because I don't ask that question.

22 Q. In over 40 years of practice you have never
23 recommended that a patient undergo prophylactic
24 surgery to remove her ovaries or fallopian tubes
25 because of her talcum powder use. Correct?

1 A. That's true.

2 Q. The patient intake form that was in use at the
3 University of North Carolina while you chaired the
4 Department of Gynecologic Oncology, did not ask
5 patients about whether or not they used talcum powder?
6 True?

7 A. That's true because we feel it is not fair to
8 make a patient feel guilty raising the issue how she
9 developed ovarian cancer once she already has it.

10 THE COURT: I guess the question is, though,
11 any of your patients that come in put aside whether
12 they have been diagnosed with ovarian cancer, if they
13 are coming in for appointments of any kind, is there
14 something that's used in the questionnaire, do your
15 forms anywhere ask that of any of the gynecological
16 patients?

17 THE WITNESS: Not at this time.

18 Q. And, in fact, Doctor, as of the date of your
19 deposition, the University of North Carolina and the
20 department that you chaired for 13 years never advised
21 women that perineal use of talcum powder can cause
22 ovarian cancer true?

23 A. I have a faculty of 75 faculties, so I cannot
24 tell you what was advised by my faculty that takes
25 care of patients that don't have ovarian cancer.

1 MS. BROWN: Permission to read, your Honor.

2 THE COURT: Yes.

3 Q. This is B-10, your February 4th, 2019,
4 deposition in this matter, page 96, lines 5 through
5 10. You were asked, Doctor:

6 "QUESTION: As of today, the University of
7 North Carolina and the department that you chaired do
8 not advise women that perineal use of talcum causes
9 ovarian cancer. Correct?"

10 There was an objection.

11 "ANSWER: That's correct."

12 A. Maybe I misunderstood the question as: Was I
13 advising? I don't know what my faculty advised.

14 Q. You have never advised your patients that talcum
15 powder use causes ovarian cancer?

16 A. So the answer from me and my patients who have
17 ovarian cancer, no, I don't advise them because I
18 think that would just add to their mental anguish and
19 guilt, that maybe they caused something which they may
20 have. It's not going to help me take care of that
21 patient that has ovarian cancer.

22 Q. Your patients are moms and sisters and aunts,
23 and you don't advise them that they should not be
24 purchasing an over-the-counter product for their
25 family that you believe causes ovarian cancer. True?

1 A. That's true.

2 Q. You have given a number of presentations over
3 the course of your career, but you had never given any
4 presentation anywhere on the relationship between
5 talcum powder and ovarian cancer. Correct?

6 A. I believe there is a chapter I wrote in 1985
7 that references talcum powder as a possible risk for
8 ovarian cancer.

9 MS. BROWN: Permission to read, your Honor.

10 THE COURT: Yes.

11 Q. At your February 4th, 2019, deposition, you were
12 asked:

13 "QUESTION: Have you ever given any
14 presentation on the relationship between talcum powder
15 and ovarian cancer?

16 "ANSWER: No."

17 You have also, Dr. Clarke-Pearson, published a
18 number of articles on ovarian cancer. Correct?

19 A. Yes. You have to show me which ones you want to
20 talk about. Most are clinical trials and treatment.

21 Q. None of those articles discuss your theory that
22 talcum powder causes ovarian cancer?

23 A. That was not the intent of any of those
24 articles.

25 Q. So the answer to my question is correct, none of

1 your articles discuss your theory talcum powder causes
2 ovarian cancer. True?

3 A. That's right, because that's not the intent of
4 any of those articles.

5 Q. You would agree with me, Dr. Clarke-Pearson, and
6 I heard you mention it this morning, that the
7 potential association between talcum powder and
8 ovarian cancer has been reported in the literature for
9 decades. Correct?

10 A. That information has been gathering over time.

11 Q. And, in fact, at your deposition you told us
12 that you yourself have been aware of the potential
13 association since your residency back in 1975.
14 Correct?

15 A. That's true.

16 Q. But the truth is, Dr. Clarke-Pearson, that it
17 wasn't until the end of 2018, after you were hired by
18 the plaintiffs' lawyers, that you formed the opinion
19 that talcum powder causes ovarian cancer. True?

20 A. No. I formed my opinion before I was hired by
21 the lawyers.

22 MS. BROWN: Permission to read, your Honor.

23 THE COURT: Yes.

24 Q. At your February 4th, 2019, deposition, page
25 104, lines 3 through 24, you were asked -- talking

1 about a video that we will talking about in a little
2 bit:

3 "You did not tell the viewers that talcum
4 powder was associated with a cause of ovarian cancer.
5 Is that right?

6 "ANSWER: That's correct. Because at that
7 point in time I didn't believe it was causative.

8 "QUESTION: It wasn't until after being
9 retained in this case and around the time that you
10 concluded your review in November of 2018, that you
11 formed that opinion."

12 There was an objection.

13 "ANSWER: As I was preparing to offer an
14 opinion I did this review and came to that opinion,
15 yes.

16 "QUESTION: If we try to put a time on it, it
17 would be toward the latter part of 2018, once you had
18 completed your review that you told us about in
19 connection with this litigation. Correct?

20 "ANSWER: Yes."

21 I want Dr. Clarke-Pearson --

22 A. Can you tell me when the video you are
23 referencing the very time is?

24 Q. I'll ask you some questions about it. We're
25 going to get to it. Right now I want to talk about

1 some other publications you had in your field over the
2 years.

3 In 1993 you authored a publication regarding
4 mutations of the p53 gene and ovarian cancer. Do you
5 recall that?

6 A. Not really. I was a co-author and that was a
7 long time ago. Do you have that in the exhibits?

8 Q. Absolutely. You were asked about this paper at
9 your deposition a few months ago. Do you recall that?

10 A. I do.

11 Q. You can find it in your binder up there,
12 Dr. Clarke-Pearson, at tab 501. We'll also bring it
13 up on the screen to aid you.

14 Do you recall, Dr. Clarke-Pearson, talking
15 about this article a few months ago in your deposition
16 and --

17 A. I'm not listening to you while I'm trying to
18 find this.

19 MS. BROWN: May I approach to help him?

20 THE COURT: Yes.

21 (Pause.)

22 Q. Have you got that in front of you?

23 A. Yes.

24 Q. This was an article you were a co-author on back
25 in 1993 regarding the p53 gene in ovarian cancer.

1 Correct?

2 A. Correct.

3 Q. And one of the things that you note in this
4 article is that approximately one-half of human
5 epithelial ovarian cancers have mutations in the p53
6 gene. Correct?

7 A. That's what we found.

8 Q. And what you concluded in this article with your
9 co-authors back in 1993 is that "p53 mutations in
10 ovarian cancer arise because of spontaneous errors in
11 DNA synthesis and repair rather than a direct
12 interaction of carcinogens with DNA. These molecular
13 data you and your co-authors noted here in your
14 article, these molecular data are consistent with data
15 from epidemiologic studies that have failed to
16 demonstrate a convincing relationship between exposure
17 to environmental carcinogens and the development of
18 ovarian cancer."

19 That's what you wrote in 1993. Correct?

20 A. That's what my lead author wrote and I was a
21 co-author, yes.

22 Q. Doctor, just to orient us as we walk through
23 your field and testimony, you told us a moment ago you
24 first became aware of the potential association of
25 talc and ovarian cancer during your residency in 1975.

1 True?

2 A. That's right, based on Johns Hopkins data from
3 Woodruff and Parmley.

4 Q. We just looked at an article from 1993 which you
5 were a co-author on in which you concluded that most
6 environmental carcinogens are not linked to p53
7 mutations. Right?

8 A. That's what that article said, yes.

9 Q. I want to take a look at another article that
10 you wrote, Dr. Clarke-Pearson, in 2009, and you can
11 find that in the very next tab in the binder in front
12 of you at 502. This is an article -- if we can bring
13 it up on the screen -- that you were in fact the sole
14 author of. Correct?

15 A. This is an invited review article from the New
16 England Journal, and I was the sole author, yes.

17 Q. And the New England Journal of Medicine we can
18 agree is a prestigious medical journal. Correct?

19 A. I said that earlier, yes.

20 Q. The article here is entitled, "Screening For
21 Ovarian Cancer." Correct?

22 A. Yes.

23 Q. One of the things you were telling us earlier
24 today is that by the time you treat patients, they in
25 many cases already have ovarian cancer. Correct?

1 A. Yes.

2 Q. But part of your research and the focus of your
3 40 years in this area has also been on how to screen
4 women for ovarian cancer and how to prevent women from
5 getting ovarian cancer. Correct?

6 A. Yes.

7 Q. And in this particular article you posed a
8 hypothetical -- you were posed a hypothetical at the
9 beginning, and the article deals with circumstances in
10 which a physician should consider screening a woman
11 for ovarian cancer. Correct?

12 A. No. It is not intended -- the article concludes
13 that we are not able to screen for ovarian cancer. So
14 I was not encouraging physicians to screen for ovarian
15 cancer because there was no mechanism in 2009 or in
16 2019 on how we can screen for ovarian cancer.

17 Q. I'm not trying to quibble with you on this.

18 A. I'm just stating what this article is intended
19 to say.

20 Q. Let's see if we can understand each other, what
21 this article is about.

22 The article starts out with a description of a
23 putative plaintiff who has come to her physician with
24 this description. Fair enough?

25 A. That's the case.

1 Q. And you review throughout the article the state
2 of knowledge of ovarian cancer, and you include a
3 discussion of some risk factors for ovarian cancer.
4 Correct?

5 A. Some risk factors.

6 Q. And your ultimate conclusion in this article is
7 this woman should not be screened for ovarian cancer.
8 Correct?

9 A. Because we don't have any screening methods to
10 use. So why would we screen.

11 Q. That's unfortunately one of the terrible things
12 about ovarian cancer is that we don't have a way to
13 screen women for ovarian cancer. Correct?

14 A. That's correct.

15 Q. And what you note in connection with this
16 article, Doctor, is your comment on that very thing.
17 And if we could look at page 2, second column, top
18 paragraph, one of the things you are talking about is
19 that because there is no obvious precursor lesion,
20 screening has to focus on early detection of invasive
21 cancer. Correct?

22 A. Where does it say "early detection"?

23 Q. Very top. Because there is no obvious precursor
24 lesion. Are you with me?

25 A. Yes. That wasn't highlighted.

1 Q. "Screening must focus on early detection of
2 invasive cancer." Correct?

3 A. That's the whole idea of any screening for
4 cancer.

5 Q. What you go on to state in this 2009 article in
6 the prestigious New England Journal of Medicine is
7 that risk factors other than age, a family history of
8 ovarian or breast cancer, and the presence of a BRCA
9 mutation are poorly understood, and approximately 90
10 percent of ovarian cancers appear to be sporadic.
11 Correct?

12 A. Yes.

13 Q. In this 2019 article, 2009 article in the New
14 England Journal of Medicine, you made no reference to
15 talc as a causative agent or a risk factor for ovarian
16 cancer. True?

17 A. There are a number of other risk factors that we
18 didn't include in that study because, again, you can't
19 screen for ovarian cancer.

20 Q. In your 2009 article in the New England Journal
21 of Medicine you make no reference to talc as a
22 causative agent in ovarian cancer. Is that correct,
23 Doctor?

24 A. I didn't make the reference to that or didn't
25 make the reference to incessant ovulation,

1 endometriosis, pelvic inflammatory disease, for
2 example.

3 Q. In fact, what you did is you called out three
4 risk factors, right? Age, family history, and BRCA
5 mutation. Correct?

6 A. Yes.

7 Q. And for the others you wrote that they are
8 poorly understood. Correct?

9 A. Yes.

10 Q. In 2011, Dr. Clarke-Pearson, you did some work
11 with the Society of Gynecologic Oncologists as you
12 have over the course of your career. Correct?

13 A. Yes.

14 Q. And you were part of a publication which can be
15 found at 530 in your binder -- and if we could bring
16 that up -- called "Pathways to Progress in Women's
17 Cancer, a Research Agenda Proposed by the Society of
18 Gynecologic Oncologists."

19 Just to orient us, Dr. Clarke-Pearson, you
20 have held some leadership positions in that
21 organization, including being the president. True?

22 A. Correct.

23 Q. And in this particular publication, Pathways to
24 Progress from 2011, your name appears here on the
25 first page as the immediate past president of this

1 Society. Correct?

2 A. Yes, as a cover letter to the membership.

3 Q. If we could look at the first paragraph of the
4 cover letter to this publication, you and the then
5 president write in the third sentence, you give a
6 little context for what this report is in fact about,
7 and you say:

8 "To make our vision a reality, SGO has in this
9 research report entitled, Pathway to Progress In
10 Women's Cancers, identified and outlined the areas of
11 research by diseases upon which the women's cancer
12 community should focus for the next decade."

13 Do you see that, Doctor?

14 A. Yes.

15 Q. So part of this publication, what this was to
16 progress in women's cancer was to identify areas of
17 research and to improve research and study in the
18 field of gynecologic cancers. True?

19 A. Certainly, that's what we want to do.

20 Q. And on page 17 of this document, Doctor, one of
21 the things that you write about is similar to what we
22 have been talking about, the idea that screening for
23 ovarian cancer is notoriously difficult. Correct?

24 A. Yes.

25 Q. And you have a section in this publication from

1 2019 that talks about how to prevent ovarian cancer or
2 what preventive action could be taken. Correct?

3 A. Yes.

4 Q. And in this section entitled "Prevention in
5 2019," you make mention of a number of risk factors
6 for ovarian cancer. True?

7 A. These are high risk factors, true.

8 Q. And those risk factors that you included in this
9 80-page Pathways to Progress document states as
10 follows:

11 "Family history and inherited risk are the
12 strongest risk factors for the development of ovarian
13 cancer but they cannot be modified. Obesity is a
14 known risk factor for the development of ovarian and
15 many other cancers."

16 Do you see that?

17 A. Yes.

18 Q. You go on to talk about protective factors for
19 ovarian cancer. Is that correct?

20 A. Yes, and I talked about them earlier today.

21 Q. Mr. Williams reminded me that I did not say the
22 year of this publication, but it was from 2011.
23 Correct?

24 A. Yes.

25 Q. So in 2011, this publication from the Society of

1 Gynecologic Oncology, which mentions prevention of
2 ovarian cancer and risk factors, did not include any
3 discussion of talc as a causative agent for ovarian
4 cancer. Correct?

5 A. That's not shown there, yes.

6 Q. And the purpose or at least the title of this
7 document is "Pathways to Progress in Women's Cancer."
8 Correct?

9 A. It's encouraging us to continue research to
10 find, for example, screening methods, other ways to
11 prevent ovarian cancer, better ways to treat it. It
12 was a comprehensive outline how we would like to
13 progress, and it was intended for many audiences,
14 including the National Cancer Institute that was not
15 funding cancer research adequately in our opinion.

16 Q. We will talk about the NCI a little bit later.
17 In the Pathway to Progress, a Research Agenda Proposed
18 for the Society of Gynecological Oncology, in which
19 your name appears in 2011, this document made no
20 mention that talc causes ovarian cancer. Correct?

21 A. From what you have shown me. I can't recall
22 this whole thing from 2011. You implied I'm the
23 author. I'm not the author of this publication.

24 Q. At this time you were the immediate past
25 president of this Society. Correct, Doctor?

1 A. I was immediate past president. I wasn't the
2 author of this publication.

3 Q. And you authored the cover page of the document
4 that follows. Correct?

5 A. Yes.

6 Q. And you referred to this research report as an
7 effort to outline areas of research in which the
8 women's cancer community should focus for the next
9 decade. Correct?

10 A. We're trying to develop an agenda for a variety
11 of audiences to encourage research, to improve the
12 outcomes of women with ovarian cancer.

13 Q. And you made no mention in your cover letter or
14 in the document itself of talc causing ovarian cancer.
15 Correct?

16 A. And other risk factors, that's true.

17 Q. Now, in 2014, Doctor, you appeared on a Fox News
18 interview. Do you recall that?

19 A. Yes. It was in Greensboro, North Carolina, a
20 very brief morning piece for women that are doing the
21 laundry that lasted about two minutes maybe.

22 Q. And I imagine you were also interested in
23 reaching women who were not doing the laundry. This
24 was an effort to reach all women --

25 A. Anyone who was available at 10 o'clock in the

1 morning, yes.

2 Q. But it was an effort to get the word out about
3 ovarian cancer, for all women, regardless of whether
4 they were folding the laundry at 10 o'clock?

5 A. Exactly. Anybody who was listening, I was happy
6 to have them hear me.

7 Q. I would like to take a look at it and ask you a
8 couple of questions about it, if we could.

9 (The video was played.)

10 Q. Now, Dr. Clarke-Pearson, we can agree, of
11 course, on this television interview, one of the
12 things you were endeavoring to do is to help women.
13 Right?

14 A. Absolutely.

15 Q. You go on in that interview to encourage women,
16 if they think they have signs of ovarian cancer, to go
17 to their doctor and ask to be checked out. Right?

18 A. That's correct.

19 Q. And one of the things you said here is "I hope
20 this clip encourages women to get better care and to
21 detect ovarian cancer earlier." Right?

22 A. Yes.

23 Q. One of the things you did in connection with
24 your effort to help women is you listed some of the
25 risk factors for ovarian cancer. Correct?

1 A. I listed some of the high risk factors, yes.

2 Q. You did not advise the Fox viewers in 2014 that
3 they shouldn't go to the drugstore and buy talcum
4 powder because it causes ovarian cancer. Correct?

5 A. That was not mentioned along with a lot of other
6 things.

7 Q. And the reason you didn't mention that,
8 Dr. Clarke-Pearson, in 2014 is because in 2014 you
9 didn't believe that talc causes ovarian cancer?

10 A. I didn't believe it, but there was certainly
11 mounting evidence that we had to start thinking
12 seriously about that issue.

13 Q. In 2014, Doctor, five years ago, you did not
14 believe the opinions that you've come into this
15 courtroom to give us today. You did not believe that
16 talc causes ovarian cancer?

17 A. I've learned a lot in the last two years.

18 Q. In fact, it wasn't until you became an expert in
19 this litigation that you came to believe that talc
20 causes ovarian cancer. Correct?

21 A. I became an expert after I believed that talc
22 caused ovarian cancer, not the other way around.

23 Q. Well, let's talk a little bit about how you got
24 involved in this litigation.

25 You know one of the plaintiffs' lawyers.

1 Correct?

2 A. Yes.

3 Q. You actually went to medical school with
4 Dr. Thompson. Correct?

5 A. Not true.

6 Q. You were at medical school at the same time.

7 Correct?

8 A. I was a resident in obstetrics and gynecology
9 when Dr. Thompson was a medical student, and I didn't
10 know her at that time.

11 Q. And it was through Dr. Thompson you got involved
12 in this litigation. Correct?

13 A. She asked me if I would evaluate whether I
14 believed talcum powder caused ovarian cancer or not
15 before I started in on my methodologic review of the
16 literature.

17 Q. At the time Dr. Thompson approached you, you had
18 been a practicing gynecologic oncologist for 40 years.
19 Correct?

20 A. Thereabouts, yes.

21 Q. At the time Dr. Thompson approached you, you did
22 not hold the opinion that talcum powder causes ovarian
23 cancer?

24 A. I didn't hold an opinion at that time. That's
25 true.

1 Q. Dr. Thompson approached you in late 2017, early
2 2018. Correct?

3 A. I don't recall exactly when.

4 Q. It wasn't until after you did a review for
5 Dr. Thompson that you came to the opinion that you now
6 hold here today. Correct?

7 A. I did a review for myself. I'm not going to go
8 out and do something for Dr. Thompson because she
9 wants me to say something for her or her firm. I have
10 a reputation, and I feel it's a strong reputation, and
11 I'm not going to sign on as somebody's hired gun. So
12 I reviewed the literature in depth and came to the
13 conclusion talcum powder causes ovarian cancer.

14 Q. You were compensated, of course, to review the
15 literature. Correct?

16 A. After I made a conclusion as to what my position
17 was, yes.

18 Q. And you submitted an invoice for your review of
19 that literature. Correct?

20 A. Yes.

21 Q. And you were compensated by the plaintiffs'
22 lawyers. Right?

23 A. As every expert witness.

24 THE COURT: Did you serve as an expert?

25 THE WITNESS: Witness, not in a product

1 liability, but in many malpractice cases.

2 THE COURT: Not in a case like this before?

3 THE WITNESS: No.

4 BY MS. BROWN:

5 Q. And so if we can work a little bit with timing
6 and this board, Doctor, is it fair to say after
7 Dr. Thompson approached you about being an expert in
8 litigation and you reviewed the literature, you came
9 to the opinion that talcum powder causes ovarian
10 cancer. Correct?

11 A. Yes, after doing a Bradford Hill analysis.

12 Q. And prior to that, though, prior to that time,
13 though, Dr. Clarke-Pearson, you were not of that
14 opinion. Correct?

15 A. I was not of that opinion.

16 Q. I want to talk a little bit about whether or not
17 this opinion that you've come to hold in the last
18 couple of years after getting involved in this
19 litigation, whether that opinion is generally-accepted
20 in your gynecologic community.

21 I want to start by talking about the American
22 College of Obstetrics and Gynecology. You would
23 agree, Dr. Clarke-Pearson, that that is a leading
24 organization in your field. Correct?

25 A. Yes, in obstetrics and gynecology.

1 Q. It is one of the premier medical associations
2 for doctors like yourself who have dedicated their
3 professional life to gynecological oncology?

4 A. The American College of Obstetrics and
5 Gynecology is more for general obstetricians and
6 gynecologists, and the Society of Gynecologic Oncology
7 is the premier organization for gynecologic
8 oncologists.

9 Q. We're going to talk about that one next. I want
10 to start with the American College of Obstetrics and
11 Gynecologists otherwise known in your field as ACOG.
12 Correct?

13 A. Correct.

14 Q. You have been a member of ACOG for decades.
15 Correct?

16 A. Yes.

17 Q. You have led numerous postgraduates and
18 continuing education courses sponsored by ACOG.
19 Correct?

20 A. Yes.

21 Q. You have served on a number of ACOG committees.
22 Correct?

23 A. Yes.

24 Q. You spoke about that with counsel this morning.
25 The gynecologic management committee is one of those.

1 Correct?

2 A. That's correct.

3 Q. You have also served a three-year term on the
4 ACOG executive board. Correct?

5 A. Yes.

6 Q. And as a practicing gynecologic oncologist, one
7 of the places you look for guidance regarding
8 potential risk factors for ovarian cancers are
9 professional organizations like ACOG. Correct?

10 A. They serve an educational role for general
11 obstetricians and gynecologists.

12 Q. You know ACOG does not recognize talc as a
13 causative agent of ovarian cancer. Right?

14 A. You have to show me the publication.

15 Q. I'll be happy to.

16 Let's take a look at, if we could -- and it's
17 in your binder, sir. If you want a hard copy there,
18 at 515. I think we have a slide we can probably use
19 for this.

20 Now, one of the things you know,
21 Dr. Clarke-Pearson, is that ACOG has a patient facing
22 website, and we spoke about it in your deposition
23 regarding risk factors for ovarian cancer. Correct?

24 A. Yes.

25 Q. And this website that ACOG, one of the leading

1 organizations in your field, maintains is frequently
2 updated to stay up to date on the latest medical and
3 scientific information. True?

4 A. Yes.

5 Q. And this page that we're looking at right now is
6 entitled, "What are the risk factors for ovarian
7 cancer?" Correct?

8 A. Yes.

9 Q. And we can see that this particular one was
10 updated just a few months ago, in April of 2019.
11 Correct?

12 A. Yes.

13 Q. And ACOG lists a number of risk factors for
14 ovarian cancer. True?

15 A. Yes.

16 Q. Some of these we have seen in your own
17 publications: age, family history, BRCA mutations.
18 Correct?

19 A. Yes.

20 Q. And some of these are new for us here, never
21 having had children. Correct?

22 A. I'm sorry?

23 Q. New for our discussion this morning. We have
24 not yet seen a publication listed, never having had
25 children, though, it's on ACOG's website?

1 A. It has been in publications over the years
2 before this. In our discussion, this is a new topic
3 such as Lynch Syndrome, and other things.

4 Q. We can certainly agree ACOG does not list talcum
5 powder as a risk factor for ovarian cancer. Correct?

6 A. We can agree.

7 Q. And certainly ACOG does not advise its people
8 who come to its website or look to it for scientific
9 advice, certainly does not advise that talcum powder
10 has been established as a cause of ovarian cancer.

11 Correct?

12 A. They haven't published that, no.

13 Q. And one of the things that ACOG has done for
14 people that look to ACOG for guidance is it in fact
15 puts out a statement regarding the alleged association
16 between talcum powder and ovarian cancer. Correct?

17 A. You have to again point me to that publication.

18 Q. Sure. In your binder, it is No. 523, and if we
19 could look at the entire document for a second, so we
20 can orient ourselves as to who this is from and what
21 is going on here.

22 What we see here, Doctor, is that in September
23 of 2017, the Executive Vice President and CEO of ACOG,
24 Dr. Lawrence, released the following statement on talc
25 use and ovarian cancer. Correct?

1600

1 A. Yes.

2 Q. And let's take a look at what the statement of
3 this leading gynecologic organization had to say. If
4 we're able to blow that up, that would be great.

5 "Despite an observed association several
6 decades of medical research have not demonstrated a
7 direct causative link between the use of talcum powder
8 and ovarian cancer. Although some case control
9 studies suggested an association, with a small
10 increase in risk, prospective cohort studies have not
11 demonstrated an increased risk. It is important to
12 note that there are limitations associated with the
13 studies that have investigated this association, which
14 includes several types of bias, inadequate sample
15 sizes, and the rarity of the disease. Because of
16 concerns regarding potential discomfort or pain,
17 obstetrician gynecologists do not recommend use of
18 vaginal treatments such as douche, vaginal sprays, or
19 talcum powder, and the use of talcum powder has
20 declined over the years. There is no medical
21 consensus that talcum powder causes ovarian cancer."

22 That was the statement from the Executive Vice
23 President and CEO of ACOG in September of 2017.
24 Correct?

25 A. Yes. I'll disagree with that, but that's what

1 he said.

2 Q. And one of the things that ACOG does in addition
3 to providing information to potential patients or
4 women with ovarian cancer or suspected ovarian cancer
5 is it also provides information for clinicians.

6 Correct?

7 A. Yes.

8 Q. And one of the things that's available on ACOG's
9 website is a PowerPoint presentation about ovarian,
10 peritoneal and fallopian tube cancer. And I would
11 like to ask you some questions about that. You can
12 find it in your binder at tab 532.

13 Now, for this PowerPoint ACOG distributes for
14 clinicians it actually goes beyond established risk
15 factors and also identifies some suspected or possible
16 risk factors. Do you see that, Doctor?

17 A. Yes.

18 Q. And this updated presentation is from January of
19 2017 and nowhere in the established or even suspected
20 or possible risk factors does ACOG identify talcum
21 powder as a risk factor for ovarian cancer. True?

22 A. That's true. It's not on this slide. I had
23 nothing to do with this slide. I don't want you to
24 imply because I was a member of some committees on
25 ACOG at one point in time that I had anything to do

1 with Dr. Lawrence's statement or this PowerPoint. I'm
2 not responsible for any of this.

3 Q. I definitely want to be clear on that. As of
4 today, you disagree with ACOG on this score. Correct?

5 A. Yes.

6 Q. When Dr. Lawrence made his statement, though,
7 back in 2017, before you were hired as an expert in
8 this litigation, you were of the view that talcum
9 powder had not been established as a cause of ovarian
10 cancer. True?

11 A. It was not my view in 2017 because I hadn't done
12 the research that I've done now.

13 Q. I would like to take a look at the most recent
14 statement from ACOG on this score, and it comes out of
15 your former committee, the Gynecologic Management
16 Committee. This is a committee opinion that can be
17 found in your binder, Doctor, at 540.

18 Now, one of the things that the ACOG
19 committees, including the ones on which you served, do
20 from time to time is they issue committee opinions.
21 Correct?

22 A. Yes.

23 Q. In fact, your resume lists some of the many
24 opinions of which you were a part of during your time
25 in service on the Gynecologic Management Committee.

1 Correct?

2 A. That's right.

3 Q. And in 2019, ACOG's Gynecologic Management
4 Committee in fact recommended the use of talc
5 following gynecologic surgery in obese women. Do you
6 see that?

7 A. This is recommended to help an abdominal wound
8 heal, by closing inflammation and scarring and closure
9 to avoid seromas forming in obese women who have thick
10 layers of fat. It has nothing to do with vaginal
11 talc.

12 Q. The Gynecologic Management Committee on which
13 you once served has recently this year recommended the
14 use of talc for women who had undergone gynecologic
15 surgery. Were you aware of that?

16 A. Yes. We're talking about abdominal incisions to
17 help them close and heal and not fall apart after
18 surgery in obese patients. It has nothing to do with
19 perineal use. They were not advising putting talc in
20 the pelvis after pelvic surgery.

21 Q. That wasn't my question. I just want to know if
22 you were aware that the committee on which you once
23 served as recently as this year is recommending the
24 medical use of talc?

25 A. Yes, I was aware of that.

1 Q. I want to talk about the Society of Gynecologic
2 Oncologists or SGO. You are familiar with that
3 organization. Correct?

4 A. Yes.

5 Q. And you have been a member of SGO for decades?

6 A. Yes.

7 Q. You in fact were the president of SGO from 2009
8 to 2010. Correct?

9 A. That's correct, '10 to '11.

10 Q. SGO describes its mission as promoting
11 excellence in the care of women at risk for or
12 affected by gynecologic cancer through advocacy,
13 education, research and interdisciplinary
14 collaboration. Right?

15 A. It sounds like our mission statement.

16 Q. And you would agree, of course,
17 Dr. Clarke-Pearson, that the doctors and the
18 scientists at SGO are working very hard to protect
19 women's health. Correct?

20 A. Yes.

21 Q. And you know that just like ACOG, SGO makes
22 available for a potential patient's or healthcare
23 provider's information about the potential risk
24 factors for ovarian cancer. Correct?

25 A. Yes.

1 Q. And you know that SGO does not identify talc as
2 a risk factor for ovarian cancer?

3 A. That's my understanding, yes.

4 Q. And you know most certainly SGO does not
5 identify talc as an agent that has been identified as
6 causing ovarian cancer. Correct?

7 A. That's what I understand, yes.

8 Q. Let's take a look at the SGO website, and we can
9 go to the slide for these.

10 Now, SGO, as you know, Doctor, actually has
11 quite a robust list of potential risk factors.
12 Correct?

13 A. I don't know what you mean by that.

14 Q. Well. We had to put it on two slides. Let's
15 take a look at what SGO advises. They list, as we've
16 discussed, the BRCA mutations. Correct?

17 A. Yes.

18 Q. They list Lynch Syndrome as a potential risk
19 factor?

20 A. Yes.

21 Q. And they list family history. Correct?

22 A. Yes.

23 Q. If we can go to the second slide, their list
24 continues to include a number of different risk
25 factors for ovarian cancer, including age,

1 endometriosis, personal history of breast cancer.

2 Correct?

3 A. Yes.

4 Q. Nowhere on this two-page list from SGO of
5 potential risk factors of ovarian cancer does talcum
6 powder appear. True?

7 A. That's true. Can you tell me when this was
8 published?

9 Q. Absolutely. This list is currently -- as we
10 downloaded it on September 12th, this is currently
11 available on SGO's website.

12 A. Okay.

13 Q. I want to talk about the Centers for Disease
14 Control and Prevention. You are aware that they also
15 advise people looking to them as a resource of
16 potential risks factors for ovarian cancer. Correct?

17 A. Yes.

18 Q. And if we could take a look at that slide.

19 Doctor, this is at tab 516. This is what the
20 Centers for Disease Control and Prevention advises
21 anyone who comes to its website, as recently as
22 June 12th, of the risk factors of ovarian cancer, and
23 they include some of the many that we looked at this
24 morning. Correct?

25 A. Yes.

1 Q. Age, right? Middle age or older?

2 A. Yes.

3 Q. BRCA mutations, which we looked at,
4 endometriosis. Correct?

5 A. Yes. All those things are on there, listed.

6 Q. You know the CDC does not advise anyone going to
7 its website or looking to it as a source of scientific
8 information, does not advise that talcum powder causes
9 ovarian cancer. Correct?

10 A. That's correct.

11 Q. And, in fact, the CDC actually recommends the
12 use of talcum powder in the genital area. Does it
13 not?

14 A. I'm not aware of that.

15 Q. Let's take a look at the slide for us, and it's
16 tab 541 in your book, Doctor.

17 Are you aware the CDC in 2015 put out some
18 guidelines related to sexually transmitted diseases?

19 A. I'm not aware of that. I'm reading along with
20 you.

21 Q. One of the sexually transmitted diseases the CDC
22 deals with is genital warts. And the CDC, as recently
23 as 2015, advised of a potential treatment for genital
24 wart pain, and what it said is that if the pain is
25 intense, powder the genital area with talc. Do you

1 see that, Doctor?

2 A. Yes, they were talking about a short-term
3 treatment for pain, not some chronic use, on a daily
4 or weekly basis.

5 Q. Well, the CDC doesn't say: Be careful not to
6 use this too long because it causes ovarian cancer;
7 does it?

8 A. Are they are talking about treating the pain?
9 Once the pain goes away, one would assume the patient
10 would stop using the treatment listed here, including
11 baking soda.

12 Q. The CDC does not advise you should weigh the
13 risks of using talcum powder for your pain because we,
14 the CDC, believe it causes ovarian cancer. Correct?

15 A. That's correct.

16 Q. You mentioned a little earlier this morning
17 "NCI." Do you remember that?

18 A. I may have said "NCI." In what context?

19 Q. In the context of looking for a governmental
20 organization to sponsor ovarian cancer research, you
21 were organizing efforts to get NCI to give more money
22 for ovarian cancer research.

23 A. That was at SGO.

24 Q. And the NCI is a part of the National Institutes
25 of Health. Correct?

1 A. Yes.

2 Q. And, in fact, some of your research has been
3 funded by NCI over the years. Is that correct?

4 A. That's correct.

5 Q. And one of the things the NCI does is it
6 produces guidance for physicians on the risk factors
7 for cancer. Are you aware of that?

8 A. No.

9 Q. Let's take a look, if we could, in your binder,
10 Doctor, at 517. If we could bring up the actual
11 document which is 517 and page 1.

12 This is a printout from the NIH, NCI website
13 regarding ovarian, fallopian tube and primary
14 peritoneal cancer prevention, and this is at the
15 health professional version. Do you see that, Doctor?

16 A. Yes.

17 Q. Did you know that NIH put out a publication like
18 this?

19 A. I was not aware of it.

20 Q. One of the things NIH and NCI do here is they
21 review the strength of the evidence for some potential
22 risk factors. And if we could take a look at page 12,
23 please, they have identified factors with inadequate
24 evidence of an association of ovarian, fallopian tube,
25 and primary peritoneal cancer. Do you see that there,

1610

1 Doctor?

2 A. Yes.

3 Q. One of the things this document from the
4 National Institutes of Health through the NCI that has
5 funded some of your research does is it identifies
6 factors that have inadequate evidence of an
7 association with perineal area risk of ovarian cancer.

8 Do you see that?

9 A. Yes.

10 Q. One of the factors with inadequate evidence that
11 NIH and NCI identified here is perineal talc exposure.
12 True?

13 A. Yes.

14 Q. And what the government cancer agency that we're
15 looking at, what they conclude here is that "the
16 weight of evidence does not support an association
17 between perineal talc exposure and an increased risk
18 of ovarian cancer."

19 Do you see that?

20 A. And the references are out of date based on
21 today's discussion.

22 Q. Let's take a look at when this document was
23 updated by the NIH, NCI, and we can find that at page
24 18?

25 See down there at the bottom the word

1 "updated." This was updated May 30th, 2019. Do you
2 see that, Dr. Clarke-Pearson?

3 A. I see that. It doesn't mean it was really
4 adequately updated. The meta-analysis that we talked
5 about this morning were in 2018, and they are not
6 included in this manuscript in terms of references.

7 Q. Have you seen this before?

8 A. No. I'm quickly looking at the reference list
9 of 50 references.

10 Q. I want to make sure you have enough time to look
11 at it.

12 A. You are talking to me, and I'm trying to read.

13 Q. I just want to direct your attention when you
14 get there, Doctor, to the updated date. Are you with
15 me?

16 A. I'm not sure where you are now. Where are you?

17 Q. Page 18 of 19 --

18 A. The date this was updated?

19 Q. Correct.

20 A. I understand that's when they published it, but
21 they haven't updated the reference list of
22 meta-analysis like Penninkilampi.

23 Q. The document we're looking at states in terms of
24 the date it was updated is May 30th, 2019. We can
25 agree on that. Right?

1 A. Yes, but they failed to include up-to-date
2 references and analysis of the issues related to
3 talcum powder and ovarian cancer.

4 Q. And what this document that we have been
5 reviewing from the NIH, NCI concludes is that the
6 weight of the evidence does not support an association
7 between perineal talc exposure and an increased risk
8 of ovarian cancer. Correct?

9 A. Based on inadequate evaluation, I've shown you
10 data today from references that are more up to date
11 that the NCI has apparently chosen or not been
12 complete in their evaluation of the topic that we're
13 talking about.

14 Q. I want to take a closer look at some of the data
15 the NCI did review. But as to the NCI's review of the
16 evidence that they state was updated in May, again,
17 that's not a process that you personally took part in.
18 Correct?

19 A. I was not involved with this, no.

20 Q. So you don't know the decision-making of the
21 scientists and professionals at NCI that went into
22 their determination that the weight of the evidence
23 does not support an association between perineal talc
24 exposure and an increased risk of ovarian cancer.

25 True?

1 A. I don't know their process or who was involved
2 in any of that, no.

3 Q. Now, let's take a look at page 12, and if we can
4 blow up that so we have it.

5 That first paragraph starts:

6 "The discussion of the scientific data on
7 perineal talc exposure and ovarian cancer." And what
8 the scientists at the NIH state is that "the results
9 from case control and cohort studies are
10 inconsistent."

11 Do you see that?

12 A. Yes.

13 Q. And it goes on to talk about a pooled analysis
14 from the Ovarian Cancer Association Consortium. Do
15 you see that?

16 A. Yes.

17 Q. You know what that is. Right?

18 A. Yes.

19 Q. That's the Terry analysis on which you rely.
20 Correct?

21 A. That's one of the many papers that we considered
22 as you got my analysis.

23 Q. And, in fact, the reason -- one of the reasons
24 you cite the Terry paper in your expert report is for
25 the proposition that it showed a dose-response. Do

1 you recall doing that?

2 A. Possibly. There are several others as well, and
3 this Terry report shows a statistically significant
4 increased risk of ovarian cancer, 24 percent, right
5 there on the bottom line.

6 Q. When it comes to the score of dose-response, the
7 reason that you cited the Terry analysis -- let's take
8 a look at what the scientists at this government
9 health organization said.

10 Now, they said that this Terry study found a
11 modest increased risk of epithelial ovarian cancer --

12 A. Statistically significant increase, yes.

13 Q. Is it important, Doctor, that it's statistically
14 significant?

15 A. It's one of the important things. Relative risk
16 is also important. Relative risk is increased by
17 24 percent.

18 Q. But in terms of evaluating a scientific study,
19 you, as a doctor, as a gynecologic oncologist, it is
20 important to you that that confidence interval shows
21 statistical significance. Is that right?

22 A. That's not the only thing. Weight of the
23 evidence is what's important.

24 Q. What these scientists say is "but the trend
25 across increasing lifetime number of applications was

1 not statistically significant."

2 Do you see that?

3 A. Yes. I'm trying to look at the references they
4 are using. The first one reference 43 was from 2003,
5 which is out of date. Terry was 2013. There are
6 other references that I've included in my report that
7 talk about dose-response. So they've cherry-picked or
8 they are just out of date with their references.

9 Q. To focus you for a second, Dr. Clarke-Pearson, I
10 want to talk about the Terry analysis from 2013. Are
11 you with me?

12 A. I'm with you.

13 Q. That is end note 44. Right?

14 A. Yes, for reference, 43.

15 Q. You and I can agree you cited this study in your
16 report for the proposition that it showed a
17 dose-response. Correct?

18 A. Along with others. The totality is what I have
19 been looking at as I make my analysis, not one paper
20 or report over another.

21 Q. And what these government scientists state in
22 this document, concluding that there is inadequate
23 evidence of an association, what they say about the
24 Terry tape is that "increasing lifetime number of
25 applications was not statistically significant."

1 Correct?

2 A. That's what that says, and there are other
3 papers that say that it is.

4 Q. And one of the studies you spoke with us about
5 this morning, Doctor, was the Schildkraut study. Do
6 you remember that?

7 A. Yes.

8 Q. That was a study from 2016. Correct?

9 A. Right.

10 Q. These folks in fact go on to talk about it,
11 correct, case-control studies of African-American
12 women in the United States. Do you see that?

13 A. Yes.

14 Q. And they go on to talk additionally about the
15 Women's Health Initiative prospective study. Correct?

16 A. Yes. One of the cohort studies. The
17 Schildkraut study showed a 44 percent increased risk
18 of ovarian cancer.

19 Q. When considering all of the evidence, they came
20 to the conclusion that perineal talc exposure was not
21 adequate to support a risk for ovarian cancer.

22 Correct?

23 A. Could you read back what she just said.

24 Q. What the scientists at the NIH concluded is that
25 there is inadequate evidence of an association between

1 perineal talc exposure and ovarian cancer. Correct?

2 A. They didn't consider all the evidence. The
3 evidence that they had, they can say that, but they
4 didn't consider all the evidence.

5 Q. Doctor, the document said it was updated two
6 months ago?

7 A. How come they didn't include references that are
8 more updated?

9 Q. You don't have any personal knowledge why they
10 did or did not include any of the references here; do
11 you?

12 A. No, I don't. It's disappointing the National
13 Cancer Institute can't publish something that's more
14 up to date.

15 Q. I want to talk a little bit, Doctor, about the
16 FDA. You know, of course, in addition to ACOG to some
17 of the other organizations we've look at, the FDA has
18 also had an opportunity to review data on the alleged
19 association between perineal talc exposure and ovarian
20 cancer. Correct?

21 A. I'm not aware of what they published.

22 Q. We talked about this a little bit in your
23 deposition. Right? You know the FDA received
24 something called a citizen's petition. You are
25 familiar with that?

1 A. I'm aware of that letter, yes.

2 Q. Let's take a look at that letter which is 506 in
3 your binder.

4 Doctor, you are familiar generally with the
5 process of a citizen's petition. Correct?

6 A. You have to explain that to me.

7 Q. You have seen, at least in connection with your
8 expert work for the plaintiffs in this lawsuit, you
9 have seen at least the documentation from the FDA
10 responding to a citizen's petition requesting an
11 ovarian cancer warning on talcum powder products?

12 A. I'm aware of that. I don't know the whole
13 process.

14 Q. I want to talk about the FDA's review of the
15 scientific data and their conclusions about whether or
16 not talcum powder causes ovarian cancer?

17 Now, this document is from 2014. Correct?

18 A. Yes.

19 Q. And as we just discussed, the FDA is responding
20 to a petition requesting that talcum powder products
21 have a warning regarding the risk of ovarian cancer.
22 Right?

23 A. Yes.

24 Q. And what the FDA concluded is that "after
25 careful review and consideration of the information

1 submitted in your petitions, the comments received in
2 response to the petitions, and review of additional
3 scientific information, this letter is to advise you
4 that the FDA is denying your petitions."

5 Right?

6 A. That's what it says.

7 Q. And what the FDA concluded is that the FDA did
8 not find that the data submitted presented conclusive
9 evidence of a causal association between talc use in
10 the perineal area and ovarian cancer. Right?

11 A. I don't know what data was submitted, and I
12 don't know what the analysis of the FDA was. This
13 organization submitted a petition in 1994 and then
14 again in 2008, and the FDA finally responded in 2014.
15 I'm not quite sure what the process is that you are
16 alluding to, but it doesn't sound very timely, and the
17 FDA doesn't reference any references whatsoever here.
18 To me this is not a publication. It's a letter
19 denying this petition.

20 Q. Let's talk about what we do know, what's
21 contained in this letter. Are you with me?

22 A. I'm with you.

23 Q. We do know this is a document from the Food &
24 Drug Administration in 2014. Right?

25 A. Right, in response to a letter from 1994.

1 Q. And 2008. See that?

2 A. Right.

3 Q. What we do know, what the FDA states in this
4 document, is that the FDA did not find that the data
5 submitted presented conclusive evidence of a causal
6 association between talc use in the perineal area and
7 ovarian cancer --

8 A. That's what this says.

9 Q. You are not aware of any other proclamation or
10 publication or document from the FDA that would
11 suggest that it has found a causal association between
12 talc and ovarian cancer?

13 A. I'm not aware of any documentation from the FDA
14 evaluating talcum powder whatsoever.

15 Q. Let's look at some of the details of the FDA's
16 evaluation in this document.

17 One of the pieces of information that the FDA
18 reviewed in connection with this document is found on
19 page 3, and it relates to the 1993 National Toxicology
20 Program report. Do you see that?

21 A. Yes.

22 Q. Doctor, in fact, you cite that 1993 toxicology
23 report in your expert report in this case. Correct?

24 A. Yes, for a different reason.

25 Q. You cite the 1993 NTP study in your report

1 following the sentence that says:

2 "Talcum powder is known to elicit an
3 inflammatory response in animals and humans."

4 Correct?

5 A. Yes, continuing my belief that chronic
6 inflammation caused by talcum powder results in
7 ovarian cancer.

8 Q. And just to orient us, let me put it up on the
9 screen so you and I are on the same page here.

10 This is your report in this case. In the
11 section entitled "Inflammation and cancer," you state:

12 "Talcum powder is known to elicit an
13 inflammatory response in animals and humans."

14 And you have three cites there. Right?

15 A. Yes.

16 Q. And one of them is this 1993 NTP study. Right?

17 A. Yes, which demonstrates inflammation caused by
18 talcum powder.

19 Q. And you know the FDA made some conclusions after
20 it had the chance to review this 1993 NTP study.

21 Correct?

22 A. Right.

23 Q. And what the FDA included, included some of
24 those criticisms in this 2014 letter. Correct?

25 A. Yes.

1 Q. And what the FDA concluded was that this 1993
2 NTP study lacks convincing scientific support because
3 of serious flaws in its design and conduct. Correct?

4 A. That's what the FDA is interpreting that.

5 Q. One of the flaws the FDA identified was that the
6 investigators used micronized talc instead of consumer
7 grade talc. See that?

8 A. That was one of their criticisms.

9 Q. From the FDA's view that resulted in the
10 experimental protocol not being reflective of human
11 exposure conditions in terms of particle size. Do you
12 see that?

13 A. I see that micronized talc is part of it, but it
14 is not the consumer grade talc. I agree with you on
15 that type.

16 Q. Do you understand there to be a difference
17 between micronized talc and the talc particles in
18 consumer grade talc?

19 A. Yes.

20 Q. You didn't mean to suggest they are the same
21 thing?

22 A. No.

23 Q. Another critique that the FDA had, was of this
24 study on which you rely in your report was that the
25 investigators conceded that they had problems with the

1 aerosol generation system. Do you see that?

2 A. Yes.

3 Q. And a final critique the FDA notes here is that
4 the study did not include positive and negative dust
5 controls which would have permitted an exact
6 assessment of the talc's carcinogenicity relative to
7 the two control dusts. Do you see that?

8 A. This study wasn't designed to look at
9 carcinogenicity. It was designed to look at chronic
10 inflammation.

11 Q. And what the scientists at the FDA concluded is
12 that in light of all of those shortcomings, there was
13 a panel of experts at an FDA workshop that declared
14 this study on which you rely had no relevance to human
15 risk. Do you see that?

16 A. Yes.

17 Q. And one of the other things the FDA did in
18 connection with the review of this request from a
19 citizen to label cosmetic talc with an ovarian cancer
20 warning is they reviewed the epidemiology. Right?

21 A. That's what they say they did, yes.

22 Q. And one of the things that the scientists at the
23 FDA determined, based on their review of the
24 epidemiology, is that a dose-response evidence is
25 lacking. Do you see that?

1 A. Yes. So, obviously, they didn't read the
2 literature that does show dose-response.

3 Q. And to be clear, Doctor, the FDA's conclusion on
4 dose-response, that is different than yours. True?

5 A. Yes. They don't even cite what references they
6 looked at to come to that conclusion.

7 Q. You disagree with the FDA's conclusion that the
8 epidemiology does not show a dose-response. Correct?

9 A. I disagree, yes.

10 Q. And you know, of course, that Health Canada,
11 they found the same thing. Right?

12 A. I didn't find a dose response. I would have to
13 look at that manuscript again.

14 Q. We can take a look at it later. If true, you
15 would disagree with that as well?

16 A. Yes.

17 Q. Another thing the FDA found in reviewing the
18 epidemiology is that a cogent biological mechanism by
19 which talc might lead to ovarian cancer is lacking.
20 Do you see that?

21 A. I see that. In 2014 it was becoming quite clear
22 in the oncologic community that chronic inflammation
23 causes cancer. So I guess the FDA missed those review
24 articles or primary articles.

25 Q. I want to talk in depth, what you are relying

1625

1 on, that a cogent biological mechanism has in fact
2 been established. Before we do that, is it fair to
3 say you disagree with the FDA on this score? Correct?

4 A. Yes, I did.

5 Q. You believe that a cogent biological mechanism
6 has been established. Right?

7 A. Yes.

8 Q. And you believe that mechanism is inflammation?

9 A. Chronic inflammation, yes.

10 MS. BROWN: Your Honor, I don't know if this
11 is an appropriate spot to stop.

12 THE COURT: We'll break now and be back in
13 45 minutes.

14 MS. BROWN: Thank you, your Honor.

15 THE DEPUTY CLERK: All rise.

16 (The luncheon recess is taken.)

17 (Continued on the next page.)

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A F T E R N O O N S E S S I O N

3 THE DEPUTY CLERK: All rise.

4 THE COURT: Thank you.

6 DANIEL CLARKE-PEARSON, resumed

8 CROSS-EXAMINATION (Continued)

9 BY MS. BROWN:

10 Q. Welcome back, Dr. Clarke-Pearson.

11 A. Good afternoon.

12 Q. Just to orient us as to where we were before we
13 took the lunch break, we were talking about the 2014
14 FDA letter. Do you recall that?

15 A. Yes.

16 Q. In fact, you and plaintiffs' counsel cited the
17 2014 FDA letter in your presentation to the Court this
18 morning. Correct?

19 A. Yes, for different reasons.

20 Q. You cited part but not all of this FDA letter.
21 Correct?

22 A. Yes.

23 Q. You agree with part but not all of the FDA's
24 findings in 2014?

25 A. The point of the FDA was there was a reasonable

1 understanding on their part that migration was
2 something they believed in and supported.

3 Q. And as it relates to the FDA's ultimate
4 conclusion that a causal association between talc use
5 in the perineal area and ovarian cancer had not been
6 established. You disagree on that score. Correct?

7 A. Yes, ma'am.

8 Q. We were talking about the FDA's finding that a
9 cogent biological mechanism by which talc might lead
10 to ovarian cancer was lacking. Do you recall that?

11 A. I see that, yes.

12 Q. The truth, Dr. Clarke-Pearson, is that no one
13 knows for sure how ovarian cancer develops. Would you
14 agree?

15 A. I think there is mounting evidence and strong
16 evidence that in the case of talcum powder, it's
17 chronic inflammation that sets off the whole cascade
18 that results in cancer.

19 MS. BROWN: Permission to read, your Honor?

20 THE COURT: Yes.

21 Q. Let's go to your deposition from February 4th,
22 and I would like to take a look at page 91, lines 19
23 through 23. At your deposition you were asked:

24 "QUESTION: Is it true that no one knows for
25 sure how ovarian cancer develops?"

1 There was an objection.

2 "ANSWER: I guess no one knows for sure."

3 Correct?

4 A. Yes.

5 Q. One of the things you spoke to us about this
6 morning was the hypothesis that incessant ovulation
7 leads to inflammation. Do you recall that testimony?

8 A. That's not a hypothesis. It seems to be
9 well-established in many studies for many years.

10 Incessant ovulation and inflammation, yes.

11 Q. And in support of that testimony you showed the
12 Court an article by Shan and Liu. Do you remember
13 that?

14 A. I'll have to see it again.

15 Q. Do you recall discussing this article this
16 morning?

17 A. Yes.

18 Q. This is a review article from 2009. Correct?

19 A. Yes.

20 Q. That's five years before you were on Fox News
21 identifying risk factors. Correct?

22 A. Yes.

23 Q. And one of the things -- and this review article
24 does not include new in vitro or in vivo research.
25 Correct?

1 A. I would have to look at the references to see
2 what's new in the article or not.

3 Q. Well, you presented this as part of your direct
4 examination. Do you remember that?

5 A. Yes.

6 Q. You would agree with me it's a review article.
7 Right?

8 A. Yes.

9 Q. It is summarizing the state of science according
10 to these authors at the time. Correct?

11 A. Okay. Up to that time.

12 Q. I think the ELMO is somehow broken.

13 MS. BROWN: One moment, your Honor.

14 (Pause.)

15 Q. This review article from 2009 that you spoke
16 about this morning reports that:

17 "In an effort to identify the causes of
18 epithelial ovarian cancer a few hypotheses have been
19 put forward."

20 Do you see that?

21 A. Yes.

22 Q. And one of the theories or hypotheses that this
23 article that you spoke about this morning discusses is
24 the incessant ovulation hypotheses. Right?

25 A. Yes.

1 Q. And it goes on to identify two additional
2 theories or hypotheses. Correct?

3 A. Yes.

4 Q. And, in fact, when you referred to the incessant
5 ovulation potential mechanism in your report, you,
6 too, referred to it as a theory. Correct?

7 A. Okay.

8 Q. Do you agree with me?

9 A. Yes.

10 Q. In fact, you reported that there are several
11 theories as to the origin of ovarian cancer. Correct?

12 A. Yes.

13 Q. And you know that the hypothesis that ovarian
14 cancer could be caused by inflammation is something
15 that has been studied for a while now. Correct?

16 A. Yes.

17 Q. And one of the articles in fact that you have on
18 your reliance list is a paper by the author Melissa
19 Merritt?

20 MS. BROWN: For the record, it's Exhibit 511.

21 Q. Now, this is a 2007 article by Melissa Merritt
22 entitled, "Talcum Powder Chronic Pelvic Inflammation
23 and NSAIDs in Relation to the Risk of Epithelial
24 Ovarian Cancer."

25 Do you see that?

1 A. Yes.

2 Q. This is one of the articles you reviewed in
3 connection with the opinion you gave to this Court
4 this morning. This was actually an epidemiologic
5 study investigating the potential mechanism of chronic
6 inflammation in causing ovarian cancer. Right?

7 A. Yes.

8 Q. And what the authors state is that "chronic
9 inflammation has been proposed as the possible causal
10 mechanism that explains the observed association
11 between certain risk factors such as talc."

12 Do you see that?

13 A. Yes.

14 Q. And what they conclude is that "chronic
15 inflammation does not play a major role in the
16 development of ovarian cancer."

17 Do you see that?

18 A. Yes.

19 Q. That's based on some of the results conducted in
20 this study in 2007. Right?

21 A. Yes.

22 Q. And what the authors of the Merritt study note
23 back in 2007 is that until the present study, no other
24 epidemiological studies appear to have tested the
25 hypothesis that ovarian inflammation is associated

1 with ovarian cancer risk. Do you see that?

2 A. Yes.

3 Q. What they go on to report in the study is a
4 number of results that support their conclusion that
5 chronic inflammation is unlikely to play a role in the
6 development of ovarian cancer. And one of those
7 findings relate to something called pelvic
8 inflammatory disease. Do you see that over here,
9 Doctor?

10 A. I do.

11 Q. Pelvic inflammatory disease is one of the
12 inflammatory conditions you spoke to the Court about
13 this morning. Do you remember that?

14 A. Yes.

15 Q. What the authors of the Merritt study say in
16 2007 is that if inflammation plays a role in the
17 etiology of ovarian cancer, it would be expected that
18 PID, or pelvic inflammatory disease would be
19 associated with an increased risk of cancer. See
20 that?

21 A. I see that. There are two types of pelvic
22 inflammatory disease. Those that are acute and
23 treated with antibiotics and others that are chronic.

24 Q. Do you see that sentence from the Merritt study?

25 A. Yes.

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1 Q. One of the things the investigators were looking
2 at was whether inflammatory conditions were at all
3 related to the risk of ovarian cancer. Right?

4 A. I understand.

5 Q. Because if your theory is that chronic
6 inflammation causes ovarian cancer, you will expect to
7 see an association between inflammatory conditions
8 like PID and ovarian cancer. Right?

9 A. In chronic pelvic inflammatory disease, yes.

10 Q. That's exactly what these investigators were
11 trying to get to the bottom of in this epidemiology
12 study that you reviewed in connection with your
13 opinions?

14 A. There are other studies that support that PID is
15 a risk factor for ovarian cancer.

16 Q. I want to talk about those. Let's focus on this
17 paragraph here and get through this article.

18 What these investigators found in the Merritt
19 paper you reviewed was that PID was not associated
20 with elevated risk of ovarian tumors in our data
21 confirming several previous reports of no association
22 with PID in studies of all subtypes of ovarian cancer.
23 Do you see that?

24 A. I see that.

25 Q. Another thing that these investigators looked at

1 was NSAIDs. Do you recall that?

2 A. Yes.

3 Q. The theory there being that, in fact, if it is
4 true that ovarian cancer is caused by an inflammatory
5 response, then an anti-inflammatory medication like
6 NSAIDs should reduce the risk. Right?

7 A. It depends what NSAIDs you study.

8 Q. That's a theory. Right?

9 A. Theory.

10 Q. These investigators looked into this, and this
11 is what they found:

12 "If inflammation did promote epithelial
13 ovarian cancer development, then it may be reasonably
14 expected that regular use of anti-inflammatory
15 medications would reduce risk. However, no overall
16 association with ovarian cancer risk was observed in
17 the study."

18 Correct?

19 A. There are other studies that show use of
20 long-term aspirin does reduce the risk.

21 Q. My question was directed to that paragraph.

22 A. This one paper in this one paragraph, I agree
23 what you read to me.

24 Q. I'm going to talk about some of the other
25 studies you showed this morning to the Court in

1 support of your opinion that ovarian cancer is caused
2 by inflammation, but I want to start just with this
3 Merritt paper.

4 What these investigators found was that there
5 was no association observed between people taking
6 anti-inflammatories, and they did not see a
7 connection. Correct?

8 A. That's correct.

9 Q. That led them to conclude that chronic
10 inflammation is unlikely to be a cause of ovarian
11 cancer. Correct?

12 A. That's their conclusion, yes.

13 Q. This was back in 2007 right, Doctor?

14 A. Yes.

15 Q. And this theory that ovarian cancer may be
16 caused by inflammation, it has continued to be
17 studied. Correct?

18 A. Yes.

19 Q. One of the studies that you showed this morning
20 in connection with your opinion that talc produces a
21 chronic inflammation that leads to cancer, one of the
22 studies you showed the Court this morning was the
23 Penninkilampi study. Do you remember that?

24 A. Yes.

25 Q. And I got a set of the slides that you guys were

1 going to use this morning. But when you did a
2 call-out from the Penninkilampi slide, that wasn't in
3 my prepared deck. So what I did was I highlighted
4 what you guys had on the screen and I want to talk to
5 you about it. Okay?

6 You spoke about Penninkilampi supporting a
7 chronic inflammatory mechanism. Do you remember that?

8 A. Yes.

9 Q. And what you guys had up on the screen is what
10 I've highlighted in pink. Do you see that?

11 A. Yes.

12 Q. It was sort of cut-and-paste. You had the
13 paragraph on the left, and there was a little space,
14 and you had that one sentence on the right. Did you
15 pick the sentences from Penninkilampi to put up?

16 A. We had some points to make like you are making.

17 Q. So you put that slide together?

18 A. With the assistance --

19 MS. O'DELL: It wasn't a slide, as you know.

20 MS. BROWN: You did it on the fly.

21 MS. O'DELL: Yes.

22 BY MS. BROWN:

23 Q. I want to talk to you about what you and counsel
24 did on the fly as it relates to what you told the
25 Court Penninkilampi stood for, and I want to talk

1 about whether that really fits with what this article
2 says.

3 So you put up what's in pink, that it's been
4 proposed that talc may ascend from the vagina to the
5 uterine tubes and create an inflammatory response. Do
6 you see that?

7 A. Yes.

8 Q. You left out the sentence above it that says:

9 "The mechanism by which perineal talc use may
10 increase the risk of ovarian cancer is uncertain."

11 Right?

12 A. Yes.

13 Q. This is the 2018 meta-analysis on which you rely
14 in your report. Correct?

15 A. Yes.

16 Q. And what the authors of this study found is that
17 the mechanism is uncertain in 2018. Correct?

18 A. Yes.

19 Q. And what they go on in the parts that were not
20 put up during your direct examination is they talk
21 about some of the reasons that the mechanism remains
22 unclear; do they not?

23 Do they not go on to talk about the proposed
24 hypothesis and some of the evidence in relation to
25 that hypothesis?

1 A. Yes. In this discussion. The meta-analysis was
2 not -- this is all their discussion that goes on
3 beyond what the findings were in the meta-analysis.

4 Q. And what they state is that it's been previously
5 proposed that talc may instigate a chronic
6 inflammatory response. That's the part you showed the
7 Court. Right?

8 A. That's part of their discussions.

9 Q. In support of their hypothesis, "It's been found
10 hysterectomy or bilateral tubal ligation in which
11 ovarian exposure to inflammatory mediators would be
12 significantly curtailed is associated with the
13 increased risk of ovarian cancer."

14 Correct?

15 A. Yes, that's what is referenced there.

16 Q. What they go on to say is that:

17 "However, the use of non-steroidal
18 anti-inflammatory drugs is not inversely associated
19 with the incidence of ovarian cancer as may be
20 expected if an etiology was related to chronic
21 inflammation"?

22 A. Could you let me take a look at the two
23 references here?

24 Q. It's A 109, and I want to talk about the part of
25 this article that you showed the Court this morning

1 that stood for the proposition that Penninkilampi --
2 that chronic inflammation is an established mechanism.
3 And the sentence I just read there, Doctor, states
4 that NSAIDs have not been inversely associated with
5 the incidence of ovarian cancer as would be expected
6 if chronic inflammation causes ovarian cancer. Right?

7 A. These two references, one of which is Merritt,
8 which you already went through, and there are other
9 references that show that the use of aspirin on a
10 continuous daily basis does reduce the incidence of
11 ovarian cancer.

12 Q. Some of those studies are very recent; aren't
13 they?

14 A. I can't remember when they were published.
15 There is evidence today, as we sit here in this
16 courtroom trying to evaluate the current evidence,
17 that aspirin does reduce the risk of ovarian cancer.

18 Q. And one of the things that folks that have
19 written those aspirin articles, scratching their head
20 about this chronic inflammation hypothesis is that
21 those very same studies that have shown a low dose
22 aspirin to be protective have not found any protection
23 with NSAIDs. Right?

24 A. Aspirin is a non-steroidal anti-inflammatory.

25 Q. Do you know the study I'm talking about, Doctor?

1 A. Remind me.

2 Q. We'll take a look at it in a minute. You know
3 there have been inconsistent findings on whether or
4 not NSAIDs and aspirin in fact reduce the risk of
5 ovarian cancer. Right?

6 A. There are some that are positive.

7 Q. And what this study that you put up this morning
8 and said, suggested that chronic inflammation was the
9 mechanism by which talc causes ovarian cancer, what
10 this study actually concludes is that the potential
11 mechanism by which genital talc is associated with an
12 increased risk of cancer, hence remains unclear.

13 Right?

14 A. So this study by Penninkilampi is not looking at
15 that issue. This is their discussion. What they have
16 is a meta-analysis looking at the risk of developing
17 ovarian cancer, being exposed to talcum powder. So
18 this is all part of their discussion about the
19 outcomes of their study and why things might have
20 happened the way they are. This is not the intent of
21 the study, to talk about anti-inflammatories or
22 chronic inflammation.

23 Q. And when you put your presentation to the Court
24 together, you highlighted what I have highlighted in
25 pink. Correct?

1 A. That's correct.

2 Q. And you testified that Penninkilampi showed that
3 chronic inflammation from talc causes ovarian cancer.
4 Right?

5 A. I don't recall testifying that it showed it, but
6 that there are other papers that do show chronic
7 inflammation as causing ovarian cancer and other
8 cancers.

9 Q. And what this article actually says is that the
10 mechanism by which perineal talc use may increase the
11 risk of ovarian cancer is uncertain. Correct?

12 A. That's what they are saying, that's correct.

13 Q. And what they actually say in this article, is
14 that NSAIDs findings have not supported the chronic
15 inflammation theory. Right?

16 A. With two references, and there are other
17 references one could use.

18 Q. And what they actually said is that the Cox-2
19 study has not supported the mechanism. Right.
20 Correct?

21 A. That's what it says right there.

22 Q. This Penninkilampi article does not support the
23 hypothesis that chronic inflammation causes ovarian
24 cancer?

25 A. The paper is a meta-analysis supporting the

1 finding that use of endometrial talc increases the
2 risk statistically of ovarian cancer.

3 Q. This is one of the most recent meta-analyses on
4 which you rely. Correct?

5 A. Yes.

6 Q. This is one of the most recent meta-analyses
7 that has been done at all on the topic of talc and
8 ovarian cancer. Correct?

9 A. Yes.

10 Q. And you put this article up this morning for two
11 propositions: one that it showed chronic inflammation
12 causes ovarian cancer. Correct?

13 A. In their discussion, yes.

14 Q. And that is not at all what this article says.
15 Right?

16 A. I think it does -- I need to speak to the Court,
17 if I can. In a scientific peer-reviewed paper, a
18 discussion does not necessarily discuss everything
19 that's in the paper. It can expand on this and become
20 more global, and that's what they are doing in this
21 discussion that we are going back and forth in yellow
22 and pink.

23 THE COURT: Okay. Let's see if you can answer
24 the question counsel just asked.

25 MS. BROWN: Thank you, your Honor.

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1 Q. This article does not state that the chronic
2 inflammation is the mechanism by which talc causes
3 ovarian cancer?

4 A. Right, that was not the intent of this article.
5 This is a meta-analysis looking at risk.

6 Q. If we go back to the transcript and we see a
7 suggestion that you said otherwise, that would be
8 mistaken?

9 A. I'm not quite sure I understand what you are
10 saying.

11 Q. You also used this article this morning to
12 suggest that it proves that talc causes ovarian
13 cancer. True?

14 A. Yes.

15 Q. Let's talk about whether what the authors
16 actually say fit the opinion that you gave on that
17 score. Okay?

18 A. Okay.

19 Q. (Reading.)

20 "The evidence for the association between
21 perineal talc use and ovarian cancer is based on the
22 body of knowledge from observable studies, and most of
23 these have been retrospective case-control studies
24 prone to recall bias?"

25 Do you see that?

1 A. I do.

2 Q. (Reading.)

3 "Hence, while perineal talc use has not been
4 shown to be safe in a similar regard, a certain causal
5 link between talc use and ovarian cancer has not yet
6 been established."

7 Do you see that?

8 A. I do. This is in the introduction to their
9 paper explaining why they undertook this
10 meta-analysis.

11 Q. The authors of the Penninkilampi paper state
12 that a causal link has not been established. Do you
13 see that?

14 A. This is in the introduction to the paper before
15 they did their study and reported their results. They
16 are explaining why they did the study because they
17 felt a causal link hadn't been established, they did
18 their meta-analysis, and now we have a relative risk
19 that's statistically significant.

20 Q. This paper did not conclude that talcum powder
21 causes ovarian cancer. True?

22 A. This paper shows a significantly elevated risk
23 of the use of talcum powder and the occurrence of
24 ovarian cancer. So I think it says it causes ovarian
25 cancer.

1 Q. Nowhere in this paper does it state that talcum
2 powder causes ovarian cancer?

3 A. I would have to look at the words throughout the
4 whole paper and look for cause. I can see what the
5 relative risk is. I could see what the statistical
6 risk is, and it increased significantly.

7 Q. This is one of the six meta-analyses on which
8 you rely. True?

9 A. And all of them showed significant increase risk
10 of ovarian cancer with the use of perineal talc.

11 Q. And this says a causal link has not been
12 established?

13 A. That's in their introduction, yes.

14 Q. What this article says is a mechanism remains
15 unclear. Correct?

16 A. That's what is in their introduction.

17 Q. And another meta-analysis that was done in 2018
18 was the Berge analysis. Correct?

19 A. Yes.

20 Q. And incidentally, Doctor, one of the things your
21 methodology here was to rely on the meta-analyses.
22 Correct?

23 A. In the end, my methodology evaluated all the
24 case-control, cohort and one pooled study, and the
25 meta-analysis. The meta-analysis I feel are more

1 powerful because they include many more studies.

2 Q. What you tell us in your report is that while
3 recent case-control studies and cohort studies are
4 compelling, you feel meta-analysis studies, because
5 they include larger numbers of patients, results in a
6 greater statistical power. Right? That's what you
7 said in your report.

8 A. Okay. If it says it in the report, yes.

9 Q. You wrote it, right?

10 A. I'm trying to find it.

11 Q. It's on the screen right at the top. Are you
12 with me?

13 A. Yes.

14 Q. So these are your words in your report, that
15 while case control and cohort studies are compelling,
16 you feel that meta-analyses are much stronger. Right?

17 A. Yes.

18 Q. Those are the words you wrote in your expert
19 report here. Right?

20 A. Yes.

21 Q. And then you created a chart of a number of
22 pooled analyses or meta-analyses. Correct?

23 A. And I failed to have one on there, which is
24 Berge.

25 Q. We spoke about Penninkilampi. That found the

1 mechanism is uncertain. Right?

2 A. That's what they say in their discussion.

3 Q. And another 2018 meta-analysis that you left off
4 of the list was the Berge meta-analysis. Right?

5 A. Yes.

6 Q. What was your methodology for creating this list
7 and how did Berge get left off?

8 A. It was clearly an oversight on my part. I'll
9 admit to human error.

10 Q. And what the authors of the Berge 2018
11 meta-analysis find on this issue of biological
12 plausibility is that the biological basis and
13 plausibility of a possible carcinogenic effect of talc
14 on the ovaries is still not understood and remains
15 questionable. Right?

16 A. Again, in their discussion it wasn't the intent
17 of this meta-analysis to determine the plausibility of
18 what the carcinogenic effect was.

19 Q. What the authors of the Berge 2018 meta-analysis
20 found is that the mechanism by which talc could cause
21 ovarian cancer is not understood and remains
22 questionable. Right?

23 A. It didn't find that in this study.

24 Q. Those are the words in the study on the page
25 that we're looking at. Right?

1 A. It didn't say that they found it.

2 Q. The opinion of the authors as documented in the
3 peer-reviewed literature in a meta-analysis that you
4 neglected to put in your report is that the biological
5 basis and plausibility of a possible carcinogenic
6 effect of talc on the ovaries is still not understood
7 and remains questionable. Correct?

8 A. Yes. It's not that they found that. They
9 didn't find that. That's just their opinion.

10 Q. And what the authors who conducted this
11 meta-analysis say in conclusion is that several
12 aspects of our results, including the heterogeneity of
13 results between case-control and cohort studies, do
14 not support a causal interpretation of the
15 association. Do you see that?

16 A. I see that.

17 Q. That is the conclusion of the authors of the
18 meta-analysis that was omitted from your report.
19 Correct?

20 A. Right. I failed to put it in the report.

21 Q. You would agree that research regarding whether
22 chronic inflammation can cause ovarian cancer is
23 ongoing. Correct?

24 A. Yes.

25 Q. And that the inflammation hypothesis is still

1 being studied in laboratories. Correct?

2 A. Yes.

3 Q. And as Her Honor asked you about earlier this
4 morning, none of those studies show that when you put
5 talc on a cell, cancerous changes occur. Right?

6 A. Right. The precursors of cancer have been
7 identified. No cancer has been seen in a cell culture
8 or laboratory.

9 Q. And you are relying on that for your opinion in
10 part on the work of Dr. Saed. Correct?

11 A. And several others.

12 THE COURT: Which other ones?

13 THE WITNESS: Shukla, Buz'Zard, Akhtar, two
14 papers.

15 Q. And you, Doctor, do not know how much talcum
16 powder a product must contain to cause inflammation.
17 Correct?

18 A. You are saying the minimum amount?

19 Q. How much? How much talcum powder causes
20 inflammation. You don't know the answer to that.
21 Correct?

22 A. Inflammation in some of these in vitro studies
23 has been induced by talcum powder. The dose the
24 investigators used in some of these studies resulted
25 in inflammation.

1 Q. You are not aware of a certain amount of talcum
2 powder that a product must contain to cause
3 inflammation. Correct?

4 A. Maybe I'm trying to paraphrase you, that I
5 should know the minimum amount that would cause
6 inflammation? Could you rephrase your question.

7 Q. Let's just look at your testimony on this score
8 from your deposition, page 223, lines 24, to 224, line
9 1:

10 "QUESTION: Is there a certain amount of
11 talcum powder that a product must contain to cause
12 inflammation?

13 "ANSWER: We don't know that information."
14 Correct?

15 A. That's correct, and that would still be my
16 answer.

17 Q. You do not believe, Doctor, that there exists a
18 threshold amount below which a woman exposed to talcum
19 powder is not at an increased risk of developing
20 ovarian cancer?

21 A. Could you say that again.

22 Q. You do not believe there is a threshold amount
23 below which a woman exposed to talcum powder is not at
24 risk for developing ovarian cancer?

25 A. Yes, we don't know.

1 Q. You do not have an opinion there is a safe level
2 of exposure to talcum powder. Correct?

3 A. No, but we know the dose-response in the studies
4 that have looked at dose response show the increased
5 risk with increasing dose.

6 Q. You do not think that there is a threshold
7 amount below which exposure to talcum powder is safe?

8 A. I don't know that threshold, no.

9 Q. You have not identified how much talcum powder
10 must reach a woman's ovaries for her to undergo
11 chronic inflammation that leads to cancer. Correct?

12 A. That's correct.

13 Q. And in your opinion, because we don't know that
14 information, any amount of talcum powder that a woman
15 uses can cause ovarian cancer. Right?

16 A. I think it increases the risk of causing ovarian
17 cancer, yes.

18 Q. You have not endeavored in this case to identify
19 a threshold dose of talcum powder below which you do
20 not believe ovarian cancer can be caused. Correct?

21 A. That's correct.

22 Q. And what that means, Doctor, is that, for
23 example, if a product contained 1 percent talcum
24 powder and 99 percent cornstarch, in your opinion,
25 that product could cause inflammation resulting in

1 ovarian cancer. Correct?

2 A. If the talcum powder was the same as Johnson &
3 Johnson's Baby Powder or Shower To Shower that was
4 included with the cornstarch hypothesis that you have
5 thrown out, then I would say that, yes -- I would
6 answer your question yes.

7 Q. Are your opinions in this case limited to only
8 Johnson & Johnson talcum powder products?

9 A. No, but since they have the market share and
10 most of the studies in epidemiology, those women were
11 using these products, that's where I stand.

12 Q. But in answering my question about a
13 hypothetical product with 1 percent talc, I thought I
14 heard you to say if that 1 percent talc was J&J talc.
15 Did I misunderstand you?

16 A. It depends on what you mean by talc. Is it
17 talcum powder J&J makes? Is it pure powder? Does
18 that talc have heavy metals, asbestos and fiber in it?

19 Q. I'm going to take J&J out of this completely.
20 If you have a hypothetical product with 1 percent talc
21 and 99 percent cornstarch, in your opinion that
22 product can cause ovarian cancer. True?

23 A. If that product had the same composition as
24 Johnson & Johnson's, then I would say true.

25 Q. Your opinion, though, when you say that is not

1 dependent on the Johnson & Johnson products
2 containing, for example, heavy metals. Correct?

3 A. It's the entire product.

4 Q. If the Johnson & Johnson products did not
5 contain heavy metals, you are still of the opinion
6 they cause ovarian cancer. True?

7 A. Yes.

8 Q. If the Johnson & Johnson products do not contain
9 asbestos, you are still of the opinion that they cause
10 ovarian cancer. True?

11 A. I'm saying the Johnson & Johnson products cause
12 ovarian cancer, whatever is in it.

13 Q. And you cannot cite to any published study that
14 supports your opinion that any amount of talc a woman
15 uses perineally leads to chronic inflammation.

16 Correct?

17 A. That's correct.

18 Q. The truth is, Doctor, not all inflammatory
19 conditions lead to cancer. True?

20 A. True.

21 Q. There are conditions that cause acute
22 inflammatory reactions purposely. Right?

23 A. Yes.

24 Q. Pleurodesis is one of those procedures.
25 Correct?

1 A. Yes.

2 Q. So pleurodesis is a procedure by which talc is
3 injected into the pleural space of a patient. Right?

4 A. Like we discussed this morning, yes.

5 Q. And the purpose of doing that is to create an
6 acute inflammatory response. Right?

7 A. Yes.

8 Q. And the idea is that the talc will absorb the
9 fluid and allow the person to breathe easier.

10 Correct?

11 A. The talc doesn't absorb the fluid. The talc
12 causes scarring between the lung and the chest wall by
13 way of an inflammatory response.

14 Q. And one of the things the scientists at IARC did
15 was they looked at people who had undergone
16 pleurodesis for a number of decades to see if they
17 developed cancer. Right?

18 A. I would have to see the studies.

19 Q. Did you review IARC's conclusion on whether or
20 not folks who had pleurodesis got cancer in connection
21 with your opinions here?

22 A. I would have to refresh my memory on that.

23 Q. You wouldn't expect somebody who underwent
24 pleurodesis and had acute inflammatory response would
25 develop cancer. Right?

1 A. I have two parts to that answer.

2 One, you are talking about acute inflammatory
3 response. I've been talking about chronic
4 inflammatory response.

5 No. 2, the majority of men and women that have
6 pleurodesis have malignant pleural effusions and don't
7 survive long enough to find out whether or not the
8 talc might also cause the cancer.

9 Q. Doctor, you are not familiar with the standard
10 of care as it relates to the use of pleurodesis. Is
11 that fair?

12 A. I use pleurodesis in my practice on thankfully
13 not a daily basis, but several times a year with women
14 who have malignant pleural effusions.

15 Q. Are you aware of the indication of pleurodesis
16 for people with benign lung conditions?

17 A. Yes. It is used for that condition too, called
18 pneumothorax, not benign. It's one lung condition.

19 Q. You are aware pleurodesis is used for people who
20 do not have cancer?

21 A. Yes.

22 Q. I want to talk a little bit, Doctor, about IARC.
23 You are, of course, familiar with IARC's review of the
24 epidemiology regarding talc and ovarian cancer.

25 Correct?

1 A. Yes.

2 Q. And you know and I can direct you -- if you want
3 a copy, we have one here for you. It is 510-A 70.
4 I'm sorry.

5 (Pause.)

6 Doctor, we are now looking at A 72, which is
7 the IARC monograph on talc that you reviewed in
8 connection with your opinions here. Correct?

9 A. Yes.

10 Q. I want to direct your attention to page 423
11 where the IARC scientists give their evaluation and
12 rationale for their classification of perineal use of
13 talc. You reviewed this. Correct?

14 A. Yes.

15 Q. You know IARC has not concluded that talc causes
16 ovarian cancer. Correct?

17 A. This is a 2010 publication based on data that
18 preceded the working group coming to this conclusion.

19 Q. One of the things, Doctor -- let's pause there
20 and talk -- first, we can agree at the time of this
21 publication IARC did not conclude, as you have done
22 here, that talc causes ovarian cancer. Right?

23 A. Yes.

24 Q. And you raise a question about what was
25 available to IARC at the time that they did this

1 review that was published in 2010. Is that right?

2 A. What was the question?

3 Q. I thought you were just raising an issue what
4 IARC would have had available at the time of this
5 review. Are you with me?

6 A. I was trying to read the report at the same time
7 you were asking the questions.

8 Q. One of the things IARC would not have had at the
9 time of this review is the 2014 Prospective Woman's
10 Health Initiative Study. Correct?

11 A. They wouldn't have had many of the studies.

12 Q. One of the things would have been one of the
13 cohort studies. Right?

14 A. Yes.

15 Q. And you know that in 2014 there was a
16 prospective cohort done as part of the Women's Health
17 Initiative. Right?

18 A. Yes.

19 Q. And that study did not find an increased risk of
20 ovarian cancer with the use of talc. Correct?

21 A. It showed an increased risk, yes.

22 Q. That study did not find a statistically
23 significant increased risk of ovarian cancer with talc
24 use. Correct?

25 A. It showed an increased relative but not a

1 statistically increased risk.

2 Q. The scientists who conducted the WHI prospective
3 study did not find a statistically significant
4 increased risk of ovarian cancer with perineal use of
5 talc. Correct?

6 A. In that one cohort study, among several cohort
7 studies, and among 20 some odd case-control studies.

8 Q. The answer to my question is "yes." Right?

9 A. The question was, it didn't find an association
10 --

11 Q. Let's do it again.

12 In 2014 the investigators at the Women's
13 Health Initiative conducted a study in which they did
14 not find a statistically significant increased risk of
15 ovarian cancer from talcum powder use. Correct?

16 A. Relative risk was increased but not
17 statistically.

18 Q. And that prospective cohort would not have been
19 available to the IARC investigators that did this
20 review. Correct?

21 A. That's true, and I think probably other studies
22 too. I would have to look at the dates of other
23 studies we have been talking about today.

24 Q. Another prospective cohort study that would not
25 have been available to the investigators doing the

1 IARC review back in 2010 is the Gonzalez study.

2 Correct?

3 A. Yes, the Sister Study.

4 Q. And that study also did not find a statistically
5 significant increased risk of ovarian cancer with talc
6 use. Correct?

7 A. The relative risk was increased but not
8 statistically. The study has many problems with it.
9 Trying to dissect one study in the totality of the
10 literature we have to look at is, I think, not
11 appropriate.

12 Q. I want to make sure I don't run over my time and
13 I get you out of here, so I'll appreciate it if you
14 listen to my question.

15 That study did not find an increased risk of
16 ovarian cancer with perineal talc use. True?

17 A. That's true.

18 Q. And that study would not have been available to
19 the investigators who conducted this IARC review.
20 Correct?

21 A. That's correct.

22 Q. In 2010, the Gates study followed up on the
23 prospective cohort that was followed in the Gertig
24 study. Correct?

25 A. Yes.

1 Q. And when the Gates investigators followed up,
2 they did not find a statistically significant
3 increased risk of ovarian cancer with perineal talc
4 use. Correct?

5 A. Increased relative risk but not statistically
6 significant increased risk.

7 Q. And that, too, would not have been available to
8 the scientists conducting the IARC review in 2010.
9 Correct?

10 A. That's correct, along with other case-control
11 studies that were not available at the time.

12 Q. There are a total of three case control-studies
13 on the issue of talc and ovarian cancer. Correct?

14 A. Three case control-studies?

15 Q. I misspoke. Three cohort studies. Correct?

16 A. Yes.

17 Q. And the Gertig, the original Gertig study has a
18 cohort that was followed up in 2010. Right?

19 A. Yes, the Nurses' study.

20 Q. In terms of what the folks do in this review
21 would have had available to them, it would not have
22 been two of the three prospective cohort studies.
23 Right?

24 A. Right.

25 Q. And they would not have had the follow-up of the

1 original cohort studies. Right?

2 A. Yes, and they wouldn't have had other
3 case-control studies.

4 Q. And one of the things in explaining the finding
5 -- first, the finding was a II-B finding in which
6 chance, bias and confounding could not be ruled out.

7 Do you remember that?

8 A. Yes. I remember what the title was.

9 Q. One of the things that the investigators in IARC
10 commented on is a topic that you spoke to us quite a
11 bit about this morning which is the possibility of
12 migration. Do you remember talking to us about that
13 this morning?

14 A. Yes, I do.

15 Q. Let's take a look, if we could, on what the
16 scientists at IARC concluded as it relates to
17 migration.

18 What these folks found is that "perineal
19 exposure to cosmetic talc in women is of concern
20 because of its possible association with ovarian
21 cancer. Several studies have been conducted in women
22 to assess potential retrograde movement of particles
23 through the reproductive tract to the ovaries."

24 Do you see that?

25 A. Yes.

1 Q. Those are some of the studies you spoke to us
2 about this morning. Right?

3 A. That is correct.

4 Q. (Reading.)

5 "These have been conducted in women who were
6 about to undergo gynecological surgery, most of whom
7 had diseases or complications of the reproductive
8 tract and organs that required surgery. The findings
9 reported in these studies may be confounded by the
10 various levels of dysfunction and clearance from the
11 female reproductive tract due to underlying
12 pathologies?"

13 That's what the IARC scientists said when they
14 did this review?

15 A. As a gynecologist, I have no understanding of
16 what that means.

17 Q. My question was: That's what the scientists who
18 did this review concluded in the IARC's published
19 monograph?

20 A. I don't think there was a gynecologist on this
21 panel. I agree with what you are highlighting.

22 Q. (Reading.)

23 "In addition, most of the studies had little
24 or no further information on the use of talc products
25 for perineal hygiene or changes in the habits that may

1 have preceded surgery."

2 A. I don't have any reason to understand what that
3 has to do with putting carbon particles or radioactive
4 microspheres in the vagina and seeing them in the
5 pelvis 24 hours later at the time of surgery. Whether
6 or not the person used perineal talc before or after
7 surgery has nothing to do with the conclusion of those
8 studies.

9 Q. I want to talk to you about the carbon particle
10 study. Let's just finish this paragraph and get right
11 to that.

12 You know, Dr. Clarke-Pearson, there is a real
13 limitation to have carbon studies in there?

14 A. Not that I know of.

15 Q. How many people were enrolled in the carbon
16 particle study?

17 A. I've forgotten. A small number.

18 Q. Three.

19 How many of them were carbon particles found?

20 A. There were carbon particles identified in the
21 pelvis.

22 Q. Two?

23 A. Two out of three.

24 Q. That study didn't deal with talc. Right?

25 A. No. It was a particle about the same size as

1 talc.

2 Q. And it didn't deal with a particle migrating
3 from the perineum to the ovaries?

4 A. No, it was in the vagina.

5 Q. The carbon particle was actually placed inside
6 the vagina near the cervix. Right?

7 A. Right.

8 Q. And the women in that study were not standing
9 up. Right?

10 A. Women stand up; they sit down; they lie down.

11 Q. Did you look at the study for how the women were
12 positioned in the carbon particle study?

13 A. They laid supine for about two hours.

14 Q. With their head down?

15 A. I think their hips were up a little bit.

16 Q. Hips up; head down. Right?

17 A. Okay.

18 Q. The women in that study, all three of them were
19 given oxycontin. Right?

20 A. They were given oxytocin.

21 Q. Oxytocin. Maybe they would have wanted that.

22 Oxytocin. Thank you, Doctor.

23 And the purpose of the oxytocin was to
24 stimulate contractions. Correct?

25 A. Yes.

1 Q. And the authors of that study in fact concluded
2 that the oxytocin could have been responsible for the
3 movement of those particles. Right?

4 A. I would agree. There are other studies that
5 show migration as well.

6 Q. I want to talk about those, too. Because you
7 said carbon particles, I want to do that one.

8 Let's talk about what the working group
9 reviewed here. On balance, the working group believed
10 that the evidence for retrograde transport of talc to
11 the ovaries in normal women is weak. Do you see that?

12 A. I do.

13 Q. "Normal women." They found that evidence to be
14 weak. Correct?

15 A. Yes.

16 Q. "In women with impaired clearance function, some
17 evidence of retrograde transport was found. Studies
18 in animals showed no evidence of retrograde transport
19 of talc to the ovaries."

20 Is that right?

21 A. That's right. There was no good animal model to
22 reproduce human anatomy. And getting back to this
23 whole idea of clearance, I don't know what they are
24 talking about.

25 Q. There is no published study, animal or human,

1 that actually traces externally applied talc in the
2 perineal region up through the reproductive tract to
3 the ovaries. True?

4 A. In animal studies?

5 Q. Or human.

6 A. I just want to make sure what we are talking
7 about. There has been no experimental study to use
8 talc in this setting of applying it, whether it's on
9 the vulva, perineum, or vagina would be unethical at
10 this point in time.

11 Q. No study at all, Doctor, that shows that talc
12 applied externally can travel up the reproductive
13 tract to the ovaries. Correct?

14 A. I think we could go to plausible -- there is no
15 study. You are right.

16 Q. In fact, there are also no studies in humans
17 that demonstrate the migration of any particulate
18 matter from the external perineum up through the
19 reproductive organs to the ovaries. Right?

20 A. That's correct.

21 Q. None of the articles that you cite in support of
22 your opinion regarding migration looked at whether
23 talc can migrate from perineal application through the
24 reproductive organs to the ovaries. Right?

25 A. That's correct.

1 Q. Let's look at literally, a bit at a quick chart,
2 if we could, which is slide 27 of the studies that you
3 cite in your report for the proposition that talc can
4 migrate to the ovaries.

5 We just talked about the Egli Newton 1961
6 study that showed in two people laying down, given
7 drugs for contractions, that carbon particles that
8 have been deposited up near the cervix were found. Is
9 that right?

10 A. The carbon particles got to the tubes and
11 ovaries.

12 Q. This is a real old study. Right, Doctor?

13 A. 1961. It's a while back.

14 Q. I don't even have the '60s on my chart. This
15 two-person carbon particle study was available well
16 before you got involved in this litigation. Correct?

17 A. Yes.

18 Q. Incidentally, Doctor, I want to make sure we are
19 clear on something. Before Dr. Thompson called you
20 and asked you to look at this literature in connection
21 with this lawsuit, this litigation, you were not of
22 the opinion that talc causes ovarian cancer?

23 A. That's what we talked about for a good bit this
24 morning already.

25 Q. I want to make sure we were clear.

1 So this 1961 studied two people. Then you
2 cite a 1971 study of a radioactive tracer. Right?

3 A. Right. Of human albumin microspheres that were
4 put in the vagina.

5 Q. This study was published decades before you got
6 involved in this litigation. Right?

7 A. Yes.

8 Q. This study had a total of 21 people and found
9 that this radioactive tracer traveled in nine of them.
10 Right?

11 A. It got to the tubes and ovaries 24 hours roughly
12 after it was applied in the vagina.

13 Q. In less than half these folks. Right?

14 A. Yes.

15 Q. Do you remember whether these folks were
16 standing up?

17 A. If a woman is going to surgery the next day, she
18 probably slept in bed the night before, supine or
19 prone, depending on how she chooses to sleep, and was
20 probably standing up to come into the operating room.
21 I think she was in a variety of positions. Had to be.

22 Q. When the radioactive tracer was placed inside
23 the vagina, she was not standing up?

24 THE COURT: The answer didn't come out on the
25 screen. The last question was: When the radioactive

1 tracer was placed in the vagina, she was not standing
2 up. Now, I need your answer.

3 THE WITNESS: I'm sure at some point in time,
4 the 24 hours before surgery, she was standing up and
5 lying down, and probably sitting.

6 Q. The question was really simple. When they
7 conducted this study and they placed the radioactive
8 tracers up near the cervix, these women were lying
9 down?

10 A. Yes, that's what I said. Also, they were
11 probably in a lithotomy position, as you do a routine
12 pelvic examination.

13 Q. The only other study you cite in the body of
14 your report that deals with particles being placed
15 inside a woman and later followed is this 2004 study
16 you see up here?

17 A. Yes.

18 Q. That one had to do with an examination done by a
19 doctor wearing cornstarch-dusted gloves. Correct?

20 A. Yes.

21 Q. And these gloves were also placed inside of the
22 women. Correct?

23 A. In the vagina.

24 Q. And in this study there were 27 people involved.
25 Correct?

1 A. Yes.

2 Q. And so in terms -- and this final study that you
3 cite doesn't involve people. It's actually a chapter
4 in a 2006 textbook. Right?

5 A. I believe so.

6 Q. And there is one sentence in there about dead
7 sperm being transported by uterine contractions.
8 Right?

9 A. I talked about that this morning.

10 Q. In terms of the total number of people who had a
11 particle inserted inside of them, and then they were
12 followed to see what happened to the particle -- we
13 are talking about 38 people. Fair?

14 A. These are experiments. Yes, 38 people, if
15 that's your count.

16 Q. That's just the thing. These are experiments.
17 Right?

18 A. Yes, and they demonstrate migration of talc --
19 migration of particles from the vagina to the tubes
20 and ovaries within 24 hours.

21 Q. And can we take a look at the graphic of the
22 positions that were described in these articles of how
23 the women were when these particles were inserted.
24 This is consistent with your review of these studies
25 in terms of women lying on their back with their heads

1 15 degrees down to the ground. Right?

2 A. Yes. I would have to look at the studies to see
3 how long they were held in this position.

4 They weren't held in this position for the
5 next 24 hours while they were waiting to undergo
6 surgery.

7 Q. In further support of your opinion that an
8 external application of talc can in fact migrate to
9 the ovaries, you cite a number of studies that looked
10 at the tissue of women, right? The Heller and the
11 Henderson studies?

12 A. The ovarian tissue found at the time of surgery.

13 Q. And if we could look at that slide, please.

14 None of the tissue studies that you cited did
15 a connection between the alleged exposure to talc and
16 the number of particles that were found. Correct?

17 A. I'm not quite sure I understand your question.

18 Q. In the Heller study, for example, they were
19 unable to show a connection between how many particles
20 were found and how much talc a person claimed to have
21 used. Right?

22 A. I guess the point that I thought you were trying
23 to make is that the talc got to the ovaries somehow.

24 Q. In the Heller study, the authors note that they
25 were unable to make a connection between reported use

1 of talc and a finding of talc in the ovaries. Right?

2 A. So some of the patients in that study had used
3 talc and others hadn't, and he found talc in both
4 groups of patients. Is that what you are talking
5 about?

6 Q. In part, Doctor. 24 people in the study.

7 Right?

8 A. And some people reported many years of talc use,
9 correct.

10 Q. There was not a correlation between increased
11 reported use of talc and an increased number of
12 particles found in the ovaries. Right?

13 A. But it showed talc particles in the ovaries.

14 Q. One of the things about that study, though,
15 Doctor, is that they looked at the pathology of one of
16 those particles and reported it. Right?

17 A. I believe so, yes.

18 Q. And there was no inflammation noted. Right?

19 A. I think the point is the talc can get to the
20 ovary from the vulva if the patients were dusting
21 themselves, or they may have gotten talc exposure when
22 they were babies.

23 Q. They found talc in the tissues of people who
24 didn't report ever using talc -- they found talc in
25 the tissue of women who never reported using it for

1 female hygiene. Right?

2 A. Female hygiene, but they may have been exposed
3 as infants.

4 Q. When they looked at a pathology slide to see if
5 that particle of talc or the particles of talc had any
6 inflammation, they didn't find it. Right?

7 A. You are talking about one slide?

8 Q. I'm talking about the reported paper.

9 A. You just mentioned one ovary they found talc in?

10 Q. The paper, you know, Doctor, because you
11 reviewed it, it reports on a review of one of the
12 slides. Right?

13 A. Right.

14 Q. And there was no inflammation found associated
15 with the talc that they found.

16 A. I don't think I have been sitting here all day
17 saying that one talc powder causes inflammation that's
18 going to cause cancer. It could, but it doesn't
19 necessarily occur in every single patient.

20 Q. Let's get that straight. I thought we just went
21 through the fact that you do not believe there is a
22 threshold of exposure to talc below which ovarian
23 cancer does not develop?

24 A. We don't know that threshold, but not every talc
25 particle necessarily causes chronic inflammation. So

1 they may not have seen it on that one microscope slide
2 of talc in that one ovary.

3 Q. So it's your testimony, Doctor, that some talc
4 reaches the ovary and some talc causes chronic
5 inflammation. Is that right?

6 A. Yes, in some patients.

7 Q. And you have not attempted to quantify how much
8 talc that reaches the ovary produces a chronic
9 inflammatory response. Correct?

10 A. No. It may not have to do with the volume of
11 talc. It may have other things to do with the
12 particular woman.

13 Q. And there are zero studies that you could point
14 the Court to that would support your position that
15 some but not all of the talc particles that get to the
16 ovary produce a chronic inflammatory response?

17 A. I believe, and there is evidence that talc
18 causes a chronic inflammatory response. It may not be
19 in every patient. Not every person that smokes
20 cigarettes three packs a day for 20 years develops
21 lung cancer. Some patients may be more susceptible to
22 the talc than others.

23 Q. And as it relates to what determines whether or
24 not a particle of talc causes chronic inflammation or
25 does not, you are not aware of any scientific

1 literature that would support that opinion. Correct?

2 A. That's true.

3 Q. Your report and your presentation --

4 MS. BROWN: Your Honor, did you want to follow
5 up on that?

6 THE COURT: Are you finished with this?

7 MS. BROWN: I was going to move to inhalation
8 briefly.

9 Q. Your report and your testimony this morning
10 suggests that you think that inhalation is a possible
11 route of exposure?

12 A. I do.

13 Q. That's not what you told us in your deposition,
14 though. Right, Doctor?

15 A. I would have to see the deposition again.

16 Q. It is true, is it not, Dr. Clarke-Pearson, that
17 you haven't seen --

18 MS. BROWN: Well, go ultimately to 219.

19 THE COURT: I thought you were reading from
20 the deposition.

21 MS. BROWN: I'll eventually do that. 219, 14
22 to 23.

23 Q. You were asked about inhalation as a potential
24 route of exposure in your deposition. Right, Doctor?

25 A. Yes.

1 Q. And your testimony was that to date we haven't
2 seen an increased risk of ovarian cancer with inhaled
3 talcum powder. Right?

4 A. Yes.

5 Q. And what you testified to is that the -- if
6 inhalation was in fact a viable pathway for talc
7 exposure to the ovaries, then you would expect in the
8 epidemiology to see an increased risk with nongenital
9 use of talc. Right?

10 A. And the Schildkraut study does show that.

11 Q. What you testified to in your deposition is that
12 we don't see that. Right?

13 A. That's what I said in my deposition. I think I
14 reread lots of these papers again, and the non-genital
15 use of talc, the talc in the Schildkraut study shows
16 an increased risk of ovarian cancer.

17 Q. You haven't attempted to compare a number of
18 nonstatistically significant findings of nongenital
19 use of baby powder with the Schildkraut finding; did
20 you?

21 A. No. I just think the Schildkraut findings are
22 data we should consider, and they raise the
23 plausibility of transport from inhalation.

24 Q. You think transport from inhalation is very
25 unlikely. Correct?

1 A. I think I said that earlier.

2 Q. In fact, you think your primary opinion is
3 related to the migration theory. Correct?

4 A. Yes.

5 Q. You testified in your deposition, in fact, that
6 powdering someone's baby with talcum powder does not
7 increase the mother's risk of ovarian cancer. Right?

8 A. If I said that in the deposition; I would say,
9 yes, that's true.

10 Q. Well, is that your opinion?

11 A. Yes.

12 Q. I heard you testify with counsel this morning
13 that you considered the totality of the evidence.
14 Right?

15 A. Yes. That's what I tried to do.

16 Q. But that is what you testified in your
17 deposition. Correct?

18 A. I don't recall testifying to that in my
19 deposition.

20 Q. You did not mention in the body of your expert
21 report any of the cohort studies. Correct?

22 A. That's true.

23 Q. You did not list on the reliance list for your
24 paper your main cites, you did not include a cite to
25 any of the cohort studies. Correct?

1 A. I'm not sure of that.

2 Q. We can look at it. What you told us in your
3 deposition is that you don't think the cohort studies
4 contribute to your review one way or another. Right?

5 A. So as individual cohort studies or as a body of
6 evidence based purely on the cohort studies, I can't
7 consider them useful in terms of going to the
8 totality, and that's what we're trying to talk about.
9 What I did was to look at the case-control studies,
10 the cohort studies, and the pooled studies, and then
11 the meta-analysis. So looking at the totality, the
12 meta-analyses, were much more helpful and stronger
13 evidence to identify the real outcome of use of talc
14 in the perineal area which increases the risk of
15 ovarian cancer in every one of those meta-analyses.

16 Q. Let's focus on the question, which was that you
17 don't believe the cohort studies contribute one way or
18 another to your review of the literature here?

19 A. They contribute to the meta-analysis, yes.

20 MS. BROWN: Your Honor, permission to read?

21 THE COURT: Yes.

22 Q. Let's look at your deposition, page 145, lines 7
23 to 17. You were asked:

24 "QUESTION: How can you validate completely
25 excluding cohort studies from your discussion?"

1 There was an objection.

2 "ANSWER: Because I don't think they
3 contribute one way or the other. They are poorly
4 designed, poorly executed, and the data that they
5 provide does not inform us at all. In fact, these
6 meta-analyses in many cases include the cohort studies
7 and still came out with a statistically significant
8 increased risk of ovarian cancer."

9 That was your testimony. Right?

10 A. Right. And the cohort studies were included in
11 the meta-analysis, so I was considering them in that
12 setting, but just not isolated as cohort studies.

13 Q. You don't think the cohort studies contribute
14 one way or the other?

15 A. They contributed to the meta-analysis; and even
16 though they were not very strong studies in many ways,
17 and were not statistically significant, they did show
18 an increased relative risk. They were included in the
19 meta-analysis, and they didn't bring down the fact the
20 meta-analysis showed a statistically significant
21 increased risk of developing ovarian cancer with
22 perineal task use. If I excluded them, the results in
23 the meta-analysis would have been even more negative
24 in the use of talc in the perineal area.

25 Q. You know the Penninkilampi meta-analysis did not

1 include the Gates follow-up in 2010?

2 A. Right. He chose to use another of the Nurses'
3 Health study.

4 Q. Two were not true. You testified at your
5 deposition that you don't think the cohorts contribute
6 one way or another?

7 A. As cohort studies just by themselves.

8 Q. I want to talk briefly about some of the
9 meta-analyses that you did include in your chart here
10 and talk about whether what the authors say fits what
11 you are using these studies for here in court. Okay?

12 A. Okay.

13 Q. Let's start, if we could, Doctor, with the
14 Huncharek 2003 study which was available at A-67 in
15 your binder at A-67. This is a 2003 meta-analysis.

16 Before we leave this table, five of the six
17 meta-analyses that you list on this table were
18 available at the time you went on Fox News in 2014 to
19 talk about ovarian cancer. Correct?

20 A. Yes. I wasn't necessarily aware of all them.
21 They are not in the GYN literature.

22 Q. Five of the six studies were published and
23 publicly available peer-reviewed scientific literature
24 at the time you went on Fox News in 2014. Correct?

25 A. That's correct, but I don't read the thousands

1 of papers published in the publically-available
2 literature every day.

3 Q. What you do is you rely in part on leading
4 public health and professional organizations to review
5 and summarize the literature that you don't get to
6 yourself. Right?

7 A. That's one source of my information for medical
8 decision-making.

9 Q. And none of those organizations, public health
10 or gynecologic communities, have concluded what you
11 concluded here that talc causes ovarian cancer?

12 A. Correct.

13 Q. Let's take a look at this article at A-67, one
14 of the six meta-analyses that you cite from 2007.
15 Let's look at what the authors of this study conclude,
16 which is that:

17 "The available observational data do not
18 support the existence of a causal relationship between
19 perineal talc exposure and an increased risk of
20 epithelial ovarian cancer. Selection bias and
21 uncontrolled confounding may account for the positive
22 association seen in prior epidemiological studies."

23 Do you see that, Doctor?

24 A. Yes, I see that.

25 Q. Huncharek 2003 explicitly states that the

1 existence of a causal relationship is not supported by
2 the data. Correct?

3 A. That's what they say in their narrative. If you
4 look at their statistics, the risk is statistically
5 increased.

6 Q. They are not talking about statistically
7 significant associations. They are talking about
8 whether the data supports a causal relationship.
9 Right?

10 A. So this is a significant risk factor that they
11 have identified as have all the meta-analysis that you
12 have there on my table plus Berge, and those all
13 increased the risk of ovarian cancer and I believe are
14 causative of ovarian cancer. If you do a Bradford
15 Hill analysis, the causation fits.

16 Q. What the authors of this paper say is that:

17 "Overall, the above findings of selection bias
18 due to study design and the clear lack of a
19 dose-response relationship between talc use and
20 ovarian cancer brings the previously suggested
21 association into question. The data presented in this
22 meta-analysis do not support a cause effect
23 relationship between perineal cosmetic talc use and
24 the risk of ovarian cancer development?"

25 Do you see that?

1 A. Yes, I do.

2 Q. You cited this study in your paper in support of
3 your opinion that talc causes ovarian cancer. Right?

4 A. And this paper, I think it's your top one on the
5 chart -- it's the third one from 2003, it's a
6 33 percent increased risk of ovarian cancer occurring
7 in talc use.

8 Q. You cite this paper in support of your opinion
9 that talc causes ovarian cancer. Correct?

10 A. That's correct.

11 Q. The paper itself states that the data do not
12 support a causal relationship. True?

13 A. That's what the authors say.

14 Q. Let's take a look at another one you cite, Gross
15 and Berg, from 1995. And that, Doctor, can be found
16 at 509 in your binder.

17 You also cite Gross and Berg in support of
18 your opinion that talc causes ovarian cancer.
19 Correct?

20 A. Yes.

21 Q. The Gross and Berg authors do not state that.
22 Fair?

23 A. Oh-oh, what exhibit is, this --

24 MS. BROWN: 509.

25 MS. O'DELL: A-509?

1 MS. BROWN: Clarke-Pearson 509.

2 Q. Let's look at what the authors of this
3 meta-analysis from 1995, and just to get our bearings
4 here, Doctor, this is way back in the 1990s. Right?

5 A. This one, I don't see it on the paper here
6 today. This paper was done before the one you just
7 talked about. So it includes less case-control
8 studies and cohort studies. So we're sort of going
9 backwards in time, the way you are doing this.

10 Q. So what we are doing is we are looking at the
11 studies that you cited in support of your opinion in
12 this court that talc causes ovarian cancer, and what
13 we're looking to see is if the authors who wrote them
14 and published them in a peer-reviewed literature said
15 the same thing.

16 A. Okay.

17 Q. Let's look at Gross and Berg and see what these
18 folks say, quote:

19 The purpose of this paper is to examine,
20 "talks about the concern of talc and ovarian cancer"
21 -- "the purpose of this paper is to examine whether
22 this concern, heightened by several epidemiological
23 studies purporting to show an increased risk is valid.
24 The conclusion reached herein is that the evidence
25 regarding the risk of ovarian cancer associated with

1 talc exposure is equivocal, and further examination of
2 the relationship is required before a sound conclusion
3 can be made."

4 Do you see that?

5 A. Yes.

6 Q. The authors of this study did not conclude that
7 talc causes ovarian cancer. Right?

8 A. That's what they are saying, yes.

9 Q. And, in fact, this meta-analysis is particularly
10 helpful as you will recall from reviewing it in
11 highlighting some concerns about meta-analyses in
12 general. Right?

13 A. I forgot if they made some commentary about
14 that.

15 Q. Let's look at what the authors who conducted
16 this meta-analysis said.

17 First of all, let's take a look at the studies
18 that they combined, and you will agree with me,
19 Doctor, if we just look at the relative risk and the
20 odds ratios we can see that only one of these studies
21 reaches statistically significant. Right?

22 A. Of these six studies -- this goes way back in
23 time. There are many, many studies since then. If
24 you look at the relative risk in the table, you are
25 showing me most are elevated. 61 percent, 40 percent,

1 10 percent.

2 Q. This is one of the six meta-analyses that you
3 chose to include in your litigation report supporting
4 your opinion that talc causes ovarian cancer.

5 Correct?

6 A. I wanted to submit the totality of the evidence
7 that is there in the medical literature, so, yes, it
8 is included in my report.

9 Q. And you forgot the most recent, Berge 2018
10 analysis?

11 A. It was a total oversight on my part. I admit
12 the errors. That wouldn't have changed the outcome of
13 my conclusions or the other meta-analyses.

14 Q. Well, look at what their conclusions were. To
15 make it easy, you can just agree with me, those
16 authors say you can't establish a causal relationship
17 on this data.

18 A. This data doesn't include a full blown
19 evaluation of Bradford Hill, which is the causation
20 that we have been talking about.

21 Q. The Berge authors from 2018 conclude that you
22 cannot make a causal relationship between talc and
23 ovarian cancer?

24 A. No, they didn't do a Bradford Hill then.

25 Q. You say it was an oversight that it wasn't

1 included, but that it would not have changed your
2 opinion at all. Right?

3 A. Right.

4 Q. We can agree, though, the authors of Berge do
5 not state that talc causes ovarian cancer?

6 A. We can agree to that.

7 Q. Let's go back to the Gross and Berg where they
8 identify some of the issues with the meta-analysis.

9 "If, for example, the issue of study bias has
10 not been properly addressed, spurious associations due
11 to small biases may reach statistical significance
12 when the studies are combined because the sample size
13 in effect has increased."

14 Do you see that?

15 A. I see that.

16 Q. They include a quote:

17 "In any one study the bias may fail to be
18 great enough to give rise to statistically
19 significant. But with meta-analyses, such biases can
20 combine so as to give rise to an overall appearance of
21 statistical significance."

22 That was a concern that these authors of this
23 meta-analysis raised in the article you cite.

24 Correct?

25 A. Yes.

1 Q. These authors also commented about limited
2 evidence supporting a dose or duration response
3 relationship. Right?

4 A. Based on the small number of cohort studies in
5 1995, yes.

6 Q. This is the 1995 meta-analysis you put in your
7 report to support your opinion. Right?

8 A. Yes, along with all the other meta-analyses and
9 the totality of the epidemiologic data.

10 Q. And what these authors state is that
11 "Given the rather low relative risks reported
12 in the studies along with the existing biases and
13 confounders that have not been adjusted for, a claim
14 for an increased risk should be viewed with some
15 suspicion?"

16 Correct?

17 A. That's what they say.

18 Q. The authors of the Gross and Berg 1995
19 meta-analysis did not conclude that talc causes
20 ovarian cancer. Right?

21 A. Right.

22 Q. Let's take a look at one more, Doctor. We're
23 almost done.

24 I want to talk to you about another
25 meta-analysis that you included which is the Langseth.

1 You can find that at A 88. And to orient us, this is
2 another meta-analysis that you put on your chart here
3 in support of your opinion that talc causes ovarian
4 cancer.

5 We can agree -- and we'll take a look, but we
6 can certainly agree that the authors of that study do
7 not agree with you. Correct?

8 MS. O'DELL: What exhibit number for Langseth?

9 MS. BROWN: A 88.

10 A. You will have to show me.

11 Q. This is the Langseth article, Exhibit A 88, that
12 you cited in your report, perineal use of talc and
13 risk of ovarian cancer. Right?

14 A. Yes.

15 Q. And what the authors of this study include in
16 their published peer-reviewed publication is a
17 proposal to the research community. Right? Do you
18 see that?

19 A. Yes.

20 Q. What the authors, having conducted this study,
21 state is that, quote:

22 "The current body of experimental and
23 epidemiological evidence is insufficient to establish
24 a causal association between perineal use of talc and
25 ovarian cancer," quote.

1 Do you see that?

2 A. I do.

3 Q. The authors of this study did not conclude, as
4 you have done here, that talc causes ovarian cancer.
5 Right?

6 A. That's what they say.

7 Q. And, in fact, one of the things they did was
8 include this forest plot of some of the studies, the
9 cohort studies that they combined in this
10 meta-analysis. Right?

11 A. Those are the studies they used in their
12 meta-analysis, and nearly all the relative risks are
13 above 1.

14 Q. And you were asked some questions about this
15 forest plot in your deposition, and you know that only
16 10 of the 20 studies included here reached statistical
17 significance. Correct?

18 A. Subsequently, there have been other studies, and
19 the majority today and the most recent meta-analysis
20 show the majority are statistically significant. So
21 you are picking a point in time before most recent
22 data is in.

23 Q. The truth of the matter, Dr. Clarke-Pearson, is
24 that the medical community as a whole does not agree
25 with the opinions that you have given to this Court

1 today. Right?

2 A. I don't know if they agree or disagree. They
3 haven't taken a stand on this.

4 Q. The gynecologic oncologist medical community has
5 not reached a consensus that talcum powder causes
6 ovarian cancer. True?

7 A. I think there is a variety of opinions in that
8 community.

9 MS. BROWN: Permission to read, Judge?

10 THE COURT: Yes.

11 Q. Let's take a look at your deposition, page 25,
12 lines 20 to 23. Your February 4th, 2019, deposition
13 you were asked:

14 "QUESTION: Has the gynecologic oncologist
15 medical community reached a consensus that talcum
16 powder causes ovarian cancer?

17 "ANSWER: As best I know, not at this time."
18 Right?

19 A. That's correct.

20 Q. The gynecologic medical community has not
21 reached a consensus on the opinions that you have
22 given to this Court today. Correct?

23 A. That's right.

24 MS. BROWN: Your Honor, I have no further
25 questions at this time.

1 THE COURT: We'll take a break for a few
2 moments.

3 THE DEPUTY CLERK: All rise.

4 (Recess.)

5 (Continued on the next page.)

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1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4 **DANIEL CLARKE-PEARSON**, resumed.

5

6 THE COURT: I want to ask a couple of
7 questions of the witness.

8 Just to follow up on a couple of the items
9 that you testified, Dr. Clark-Pearson, first on some
10 of the questioning at the end of the questioning on
11 inflammation, and when you indicated not every talc
12 particle is going to cause inflammation. Correct?

13 THE WITNESS: Yes.

14 THE COURT: Your answer in that regard was in
15 trying to explain that it depends on the woman.

16 THE WITNESS: That's part of it. The immune
17 system of that woman, where that talc particle lies,
18 those are the variables.

19 THE COURT: Those are the basic variables as
20 to why it makes a difference?

21 THE WITNESS: I think so. And I think the
22 tissues' susceptibility of the ovary may vary a little
23 bit from one woman to another. We're not saying talc
24 is causing cancer in the vagina or cervix or uterus.
25 The ovary itself, I believe, is susceptible for

1 reasons that are not clear.

2 THE COURT: You said "for reasons that are not
3 clear"?

4 THE WITNESS: Yes. That I think likewise we
5 don't know exactly why smoking causes lung cancer.
6 There's chemicals there, but exactly what it causes
7 and why some people smoke and don't get cancer and
8 others do, the immune system is probably a big part of
9 it, the genetics of the patient.

10 THE COURT: The last question, and I asked you
11 this this morning, following on the inhalation theory.
12 Just to press you a little bit more on that, which is
13 I think you have been very candid to say you've used
14 the words "very unlikely that it will happen."

15 THE WITNESS: Okay.

16 THE COURT: But, nonetheless, you continued to
17 assert that it's plausible that it can.

18 THE WITNESS: There is evidence -- I guess I'm
19 extrapolating from asbestos particles itself and those
20 talcum powder has asbestos in it or not --

21 THE COURT: That's something that's an open
22 question in this case.

23 THE WITNESS: Yes.

24 THE COURT: If you were to take the asbestos
25 out of it, would you still have the same opinion on

1 inhalation?

2 THE WITNESS: Probably less so.

3 THE COURT: So there is a difference in your
4 opinion if it were found not to have asbestos?

5 THE WITNESS: Yes.

6 THE COURT: You think it's the asbestos
7 quality of it as one of the components that makes the
8 inhalation theory more plausible?

9 THE WITNESS: Yes.

10 THE COURT: Even if still very unlikely?

11 THE WITNESS: And, again, based on IARC
12 findings that inhaled asbestos can get into the ovary.

13 THE COURT: I think I have where you are on
14 that. But I'll still end by saying, I don't think
15 that's where the bulk of your opinion lies.

16 THE WITNESS: No. You are correct. Thank
17 you.

18 THE COURT: Thank you, Ms. O'Dell. None of
19 that counted toward you.

20 MS. O'DELL: May I expand on the question that
21 your Honor asked?

22

23 REDIRECT EXAMINATION

24 BY MS. O'DELL:

25 Q. Dr. Clarke-Pearson, you mentioned asbestos

1696

1 fibers in relation to inhalation and that impacts your
2 opinion. Would that also be true for talc fibers or
3 fibrous talc?

4 A. Sure. If I didn't say it just now, yes, I'll
5 answer your question by saying fibrous talc would be
6 the equivalent of impact, as talc has asbestos fibers.

7 Q. Thank you.

8 At the end of Ms. Brown's questioning she was
9 asking you about consensus in the medical community,
10 and then she asked you questions about consensus in
11 the GYN oncology community. Do you recall those
12 questions?

13 A. Yes, I do.

14 Q. Can there be differences of opinion in the
15 medical community?

16 A. There are always differences of opinion where
17 there is clinical decision-making or policy. So, yes,
18 I think there are differences of opinion. I think
19 right now the medical community is silent on the
20 topic. I'm not sure there is a difference of opinion.

21 Q. In regard to your opinion based on your review
22 of the evidence, the totality of the evidence, is it
23 your opinion that there is -- it is biologically
24 plausible that talc can reach the ovary?

25 A. Can reach the ovary, that's the first question,

1 yes.

2 Q. Based on your review of the evidence, is it your
3 opinion that talc, once it reaches the ovary or the
4 Fallopian tube, causes chronic inflammation?

5 A. Yes.

6 THE COURT: What can cause chronic
7 inflammation? Based on your previous testimony, it's
8 not going to cause it in every case.

9 THE WITNESS: Right. All the things I had on
10 that one graphic -- endometriosis, chronic pelvic
11 inflammatory disease, obesity.

12 Q. Based on those two facts, is it your opinion in
13 this case, having considered the totality of the
14 evidence, that it is biologically plausible that the
15 genital use of talc can cause epithelial ovarian
16 cancer?

17 A. Yes.

18 Q. I'm going to change topics.

19 Doctor Clarke-Pearson, I'm going to skip
20 around to try to address a few things.

21 You were asked a number of questions about
22 whether you considered the cohort studies in reaching
23 your opinion. You gave testimony about that earlier?

24 A. Yes.

25 Q. You recall that?

1 A. Yes.

2 Q. Did you read the cohort studies prior to
3 reaching your opinions in this case?

4 A. Yes. I just didn't acknowledge them maybe the
5 way people wanted me to in my report.

6 Q. And, in fact, are the cohort studies part of the
7 reliance materials that you included at the back of
8 your report?

9 A. Yes. And that was part of the totality of my
10 assessment.

11 Q. And, also, in regard to the Berge study, you
12 were very forthright to say it was an omission not to
13 include it in the chart of meta-analyses, and you've
14 talked about that.

15 A. Right.

16 Q. Did you consider the Berge study prior to
17 reaching your opinions in this case?

18 A. I did. I just didn't happen to have it on my
19 table in my report.

20 Q. In fact, did you include the Berge study in your
21 reliance materials that were included in the back of
22 your report?

23 A. I believe so, if you look at that reference
24 list.

25 Q. I will.

1 Dr. Clarke-Pearson, did you include Berge in
2 your reliance material?

3 A. Yes, it's right there on the reference list.

4 Q. I think Ms. Brown was alluding to the cited
5 references and suggested that you had not included it
6 in your report, but in fact you had. Correct?

7 A. I see, yes.

8 Q. There were also questions regarding the 2010
9 IARC monograph, the talc monograph pertaining to talc
10 without asbestos fibers.

11 A. Yes.

12 Q. You were asked a series of questions regarding
13 their findings in that particular monograph. Let me
14 ask you a couple of questions.

15 In IARC 2010, did they consider the data after
16 2006?

17 A. In their references, the citations that they
18 had, go up to I think just to 2006. There is a
19 four-year gap of information that was coming out into
20 the medical literature that were not considered.

21 Q. In fact, if you looked at the charts we looked
22 at earlier, the forest plots that were part of our
23 original presentation, would it be fair to say that
24 all of the case-control studies after Wu, Rosenblatt,
25 Kurta, Wu, 2015, Cramer and Schildkraut were not a

1700

1 part of IARC's consideration for the 2010 monograph?

2 A. Right. They couldn't have known that because it
3 was after they published.

4 Q. And also, in regard to the IARC 2010 monograph,
5 did they consider the meta-analyses that you've
6 discussed here today that were published after 2006,
7 and that would include Langseth 2008, Berge 2018,
8 Taher 2018, not published -- excuse me I skipped
9 Penninkilampi -- Penninkilampi 2018 and Taher 2018,
10 and then also Terry 2013, were those a part of IARC
11 2010 analysis?

12 A. They couldn't have been because they were
13 published subsequent to that which adds, again, to the
14 totality of what I have been trying to talk about
15 today.

16 Q. Before lunch Ms. Brown asked you about a
17 reference, a publication that you wrote for the New
18 England Journal of Medicine relating to screening for
19 ovarian cancer. Do you recall those questions?

20 A. I do, yes.

21 Q. She directed your attention -- by the way, was
22 this an invited review of the New England Journal of
23 Medicine?

24 A. Yes. I was asked as an expert to write a review
25 paper, so it took a fair amount of time to review the

1 world's literature on this topic.

2 Q. Did you consider that to be an honor?

3 A. Yes.

4 Q. Looking at the section Ms. Brown directed you to
5 that addressed risk factors, it says:

6 "Risk factors other than age, a family history
7 of ovarian cancer, breast cancer, and the presence of
8 BRCA mutation are poorly understood and approximately
9 90 percent of ovarian cancers appear to be sporadic."

10 Did you include in that recitation of risk
11 factors any inflammatory risk factors that we
12 discussed this morning?

13 A. No. The risk factors I listed are the ones that
14 are high risk like BRCA mutations.

15 Q. Would those be considered genetic risk factors?

16 A. Yes.

17 Q. And for that reason, because they were genetic
18 risk factors as opposed to inflammatory risk factors,
19 would it have been appropriate to list other risk
20 factors such as talc usage?

21 A. The paper was intended to identify patients to
22 discuss whether screening was possible at all, and the
23 answer was no; and it still is no on the one hand,
24 discouraging physicians from doing testing, such as
25 ultrasounds or CA-125 blood tests, which at that point

1 were proven to be not useful but they were still being
2 done and to encourage the medical community to do more
3 research to identify screening techniques, and we
4 still haven't gotten there in the 10 years since I
5 published that paper. It wasn't intended to review
6 all risk factors.

7 Q. Dr. Clarke-Pearson, you were asked about the NCI
8 publication, "Ovarian Fallopian Tube and Primary
9 Peritoneal Cancer Prevention," the PDQ as it's
10 referred to. Do you recall the line of questions Ms.
11 Brown asked about?

12 A. I do remember some. Some of my comments were
13 the references were pretty far out of date.

14 Q. Let's turn and look at the five references that
15 are related to ovarian cancer and talcum powder usage.

16 You see 43 through 47, Huncharek 2003. Is
17 that one of the meta-analyses that you included in the
18 chart that we looked at earlier?

19 A. Yes, it was one of the older ones.

20 Q. Did it include there was an increased risk in
21 the use of talcum powder for that ovarian cancer?

22 A. The answer is yes, about a 33 percent increased
23 risk that was statistically significant.

24 Q. And also for the PDQ, they cite the Terry paper.
25 Do you recall that?

1 A. The pooled analysis.

2 Q. And in the Terry paper did they include that
3 there was a 1.24 increased risk of ovarian cancer that
4 was statistically significant?

5 A. Yes. It's highlighted there.

6 Q. And, further, while I'm on the Terry paper, let
7 me follow-up on another item Ms. Brown asked you
8 about, and, specifically, on whether the Terry paper
9 showed a trend toward dose-response. Do you recall
10 those questions?

11 A. I recall that, and it does show a trend.

12 Q. In fact, does the paper include a table that
13 outlines the statistically significant results of the
14 increased risk for certain quartiles of usage?

15 A. Yes.

16 Q. Is this the table that shows that there was a
17 statistically significant trend in dose for the Terry
18 study?

19 A. Yes.

20 Q. And go further, so we've discussed Huncharek
21 cited by the NCI that showed an increased risk. We've
22 discussed Terry cited by NCI, which also showed or
23 demonstrated an increased risk. And then they go to
24 Schildkraut. And in the Schildkraut paper, of course,
25 you and I discussed that this morning, was there a

1 statistically significant increased risk for ovarian
2 cancer?

3 A. Yes. In the specific population of
4 African-American women from, I think, 11 different
5 areas of the United States.

6 Q. In the Schildkraut paper -- and could we put it
7 up on the screen? It's Exhibit 8. It's General
8 Causation Opposition Exhibit 8. If you could go to
9 page 1416 of the publication, which I think is the
10 next to the last page.

11 On the left side, the lower paragraph there,
12 Doctor, did the researchers in the Schildkraut study
13 write:

14 "The results of the current study showed that
15 genital powder use was associated with ovarian cancer
16 risk in African-American women and are consistent with
17 localized chronic inflammation in the ovary due to
18 particulates that travel through a direct transvaginal
19 route. The dose-response observed for duration of
20 genital powder use provides further evidence for the
21 relationship between genital powder and overall EOC
22 risk. Our data suggests that the increased risk due
23 to the use of genital powder applies to both serous
24 and non-serous histologic subtypes."

25 Is that what they concluded?

1 A. Yes, that was their conclusion.

2 Q. Is that consistent with your opinion?

3 A. Yes. In the paper and the totality as well.

4 Q. Going back to the PDQ, we talked about
5 Huncharek, Terry, Schildkraut, Gertig.

6 Dr. Clarke-Pearson, did the Gertig study, one
7 of the cohort studies show a statistically significant
8 increased risk in serous ovarian cancer?

9 A. In serous ovarian cancer, which is the most
10 common histologic type of the epithelial ovarian
11 cancers, yes, they did.

12 Q. Based on the fact NCI cited five references, and
13 the four we have gone through show a statistically
14 significant increased risk, is it somewhat baffling to
15 understand how the NCI concluded there was no data to
16 support a relationship between the genital use of
17 talcum powder and ovarian cancer?

18 A. It's baffling, and, at the time this is a very
19 recent publication. There is so much other literature
20 equivalent to those four articles you just presented
21 to me that exist that could have been analyzed. I'm
22 disappointed the NCI isn't doing a better job of doing
23 good comprehensive research.

24 Q. You were asked some questions -- I'm going to
25 transition to another topic. You were asked questions

1 about some of the studies that you relied on in
2 connection with your opinion that talcum powder can
3 migrate to the fallopian tubes and ovaries. And, in
4 particular, counsel for Johnson & Johnson stated in
5 relation to the Venter paper, that the Venter paper
6 does not support your opinion that talc can migrate.
7 Do you recall that line of questioning?

8 A. I've forgotten it.

9 Q. That's fair enough. You've had a long
10 afternoon.

11 Take a look at the Venter paper, which is
12 general causation opposition 70.

13 The Venter paper discusses the migration of
14 radioactive tracers?

15 A. Right. Albumin microspheres that are
16 radioactive.

17 Q. And in the discussion section of the paper,
18 let's look at the conclusion that the authors reached
19 there.

20 Based on their study, this experiment, they
21 stated:

22 "Evidence is available for migration of
23 different substances in either direction within the
24 female reproductive system between the peritoneal
25 cavity and ovaries via the tubes, uterus, and the

1 vagina, and out."

2 Is that supportive of your opinion that the
3 female reproductive system is an open system?

4 A. Yes, it goes both ways.

5 Q. They go on to say:

6 "Various living organisms actively follow this
7 pathway in both directions. Gases, fluids, bias and
8 contrast media can easily be introduced from the
9 vagina into the peritoneal cavity. If the transit can
10 take place so easily, it is probably the same for many
11 chemical substances used for hygienic, cosmetic, or
12 medicinal purposes, many of which may have potential
13 carcinogenic or irritating properties."

14 Is that also true of talcum powder?

15 A. Yes.

16 Q. You were asked a series of questions about one
17 of the Huncharek papers, and this in particular was
18 the Huncharek 2003. There are three of the Huncharek
19 papers, but this is 2003, and it was marked by
20 Ms. Brown as A 76. Do you recall that? Ms. Brown
21 directed you to the material I have highlighted in
22 pink.

23 Ms. Brown highlighted, walked you through what
24 I have highlighted in pink:

25 "The available observational data do not

1 support the existence of a causal relationship between
2 perineal talc exposure and an increased risk of
3 epithelial ovarian cancer."

4 I'm sure she was pressed for time. She missed
5 a paragraph here. It goes on to say:

6 "These statistical associations raise concerns
7 that there may be a cause effect relationship between
8 perineal talc exposure and ovarian cancer
9 carcinogenesis. This is further confirmed by the
10 structural similarities between talc and asbestos, a
11 well-recognized human carcinogen."

12 Did the authors state that?

13 A. Yes, they did.

14 Q. Let's go to one more of the studies that
15 Ms. Brown directed you to. It was the Gross and Berg
16 study. Do you recall that?

17 A. Yes.

18 Q. That was one of the early meta-analyses that you
19 reviewed?

20 A. Yes.

21 Q. Dr. Clarke-Pearson, why is it important when you
22 are looking at meta-analyses to review and rely on the
23 most recent meta-analyses?

24 A. Well, I think we want to look at all of the
25 data, and that particular paper was early on, and

1 there were very few studies that had been completed at
2 that time. So there is nothing wrong with that
3 meta-analysis, but there are more up-to-date
4 meta-analysis that are much stronger in helping us
5 come to a conclusion about risks.

6 Q. Did the most recent meta-analyses due to the
7 fact that they analyze, I think you said, 27 studies
8 this morning, do they have greater statistical power?

9 A. Yes, they do.

10 Q. And because of that, would they provide further
11 information regarding the true risk between genital
12 talc use and ovarian cancer?

13 A. Yes, they are the most up-to-date information we
14 could base decisions on.

15 Q. Let me ask you to look at the Shan and Liu --
16 it's General Causation Opposition Exhibit 109. If we
17 could put that on the screen.

18 Ms. Brown discussed with you the first page of
19 this paper, on the right-hand side at the top, and
20 right under "Etiology of EOC Inflammatory in Nature."
21 Do you see that section?

22 A. Yes.

23 Q. Just for those of us who don't operate in the
24 medical community all the time, what does "etiology"
25 mean?

1710

1 A. The reason that some event happens, I guess, if
2 I can put it in a generic term, why something happens.

3 Q. Ms. Brown directed you to the first sentence:

4 "EOC is perhaps one of the most sinuous human
5 cancers. In an effort to identify the causes of EOC,
6 a few hypotheses have been put forward" and she
7 suggested that inflammation was a hypothesis. Do you
8 recall that?

9 A. The incessant ovulation, we're talking
10 hypotheses and inflammation being one, she was
11 suggesting.

12 MS. O'DELL: And, Cory, if you could put it on
13 the screen, I think it's page 3108 of the article, the
14 second page of the publication.

15 Q. On the right-hand side, second paragraph at the
16 beginning. The authors write:

17 "Because inflammation is known to be a causal
18 factor in promoting tubal tumorigenesis the hypothesis
19 that a portion of serous ovarian carcinomas may
20 originate in the fallopian tube provides another link
21 although indirect between inflammation and EOC."

22 Does that support your opinion,
23 Dr. Clarke-Pearson, and is this one of the reasons you
24 cited this particular paper?

25 A. That, and it ties in with earlier this morning

1 talking about the fallopian tube making a contribution
2 to cause serous ovarian cancer.

3 Q. Let me direct you now, Dr. Clarke-Pearson, to
4 the Penninkilampi paper. We discussed that quite a
5 bit today.

6 A. Yes.

7 Q. If you'll turn to page 2 of the publication,
8 and, for the record, it is General Causation
9 Exhibit 62. It's page 42 of the publication.

10 Ms. Brown directed you to the upper left
11 column at the top, end of the paragraph, and she read:

12 "The association between perineal talc use and
13 ovarian cancer is based on the body of knowledge from
14 observational study, and most of these have been
15 retrospective case-control studies prone to recall
16 bias. Hence, while perineal talc use has not been
17 shown to be safe, in a similar regard a certain causal
18 link between talc use and ovarian cancer has not yet
19 been established."

20 Do you recall her reading that to you?

21 A. Yes.

22 Q. It's reference 8 and 9, and reference 8 is
23 Huncharek 2011. And just for ease, let me just put
24 Huncharek 2011 on the ELMO. It's General Causation
25 Opposition Exhibit 155.

1 Is this one of the meta-analyses you reviewed
2 in reaching your opinions in this case?

3 A. Yes.

4 Q. And looking at the results of the meta-analyses,
5 did they conclude:

6 "These reports show roughly a 30 to 60 percent
7 increased risk of ovarian cancer associated with
8 perineal talc exposure."

9 A. That's what I have been saying all day, yes.

10 Q. And, in fact, on page 5 of the publication
11 Huncharek 2011 -- it's page 5 on the copy I have.

12 MS. BROWN: I don't think Huncharek 2011 is
13 one he relied on.

14 MS. O'DELL: It's on his reliance list.

15 Q. Let me put it on the ELMO. Huncharek 2011 was
16 another publication by Huncharek and others, and you
17 see it says here:

18 "Asbestos fibers in the lung initiate an
19 inflammatory and scarring process, and it has been
20 proposed that talc as a foreign body might initiate an
21 inflammatory response."

22 There is one other section let me just go to
23 quickly.

24 MS. BROWN: What's the exhibit number?

25 MS. O'DELL: 155.

1713

1 Q. Doctor, I think I picked up the wrong Huncharek.
2 I think there are three of them. I'll come back to
3 that.

4 Back to Penninkilampi. Penninkilampi cited
5 for purposes of the conclusion that -- or, the
6 statement that Ms. Brown directed you to, it says --

7 MS. O'DELL: I may need a technical assistant
8 on this.

9 (Pause.)

10 Q. Ms. Brown took you to this statement regarding a
11 certain causal link between talc use and ovarian
12 cancer has not yet been established, and we looked at
13 Huncharek, and it did show a statistically significant
14 increased risk. And it also cites Langseth, and
15 Ms. Brown asked you about the Langseth paper, and she
16 directed you to certain portions, but let's go back
17 and take a look at other portions.

18 On page 1 of the Langseth study,
19 Dr. Clarke-Pearson, it says:

20 "From pathology studies it is known that
21 particles and fibers can enter the body and migrate to
22 distant organs. For instance, asbestos fibers have
23 been found in ovaries for women exposed to asbestos.
24 Analogously following the perineal application talc
25 particulates can migrate from the vagina to the

1 peritoneal cavity in the ovaries."

2 Does that support your opinion regarding
3 migration?

4 A. Yes, it does.

5 Q. Further in the Langseth study I think Ms. Brown
6 focused your attention on this portion that talked
7 about proposal:

8 "The current body of experimental and
9 epidemiological evidence is insufficient to establish
10 a causal association between perineal use of talc and
11 ovarian cancer. Experimental research is needed."

12 They focused your attention on that portion of
13 the study. Correct?

14 A. Correct.

15 Q. If you turn over to the back, I think you had
16 time to go to this, it says, quote:

17 "The mechanism of carcinogenicity may be
18 related to inflammation. This paper focuses on the
19 high degree of consistency in the studies accomplished
20 so far, and what should be the focus in future
21 studies."

22 Does that also support your opinion that it is
23 biologically plausible that talcum powder can reach
24 the ovary and cause chronic inflammation?

25 A. Yes, both events are plausible and necessary to

1 support the causation of talc causing ovarian cancer.

2 Q. Two more topics.

3 The CDC has this as part of their website.

4 Ms. Brown showed you this earlier. She put it on the
5 screen with a slide, but in our books we got a
6 printout from the website. It lists risk factors for
7 ovarian cancer, and you walked through those earlier.

8 Right?

9 A. Yes.

10 Q. And has the CDC sponsored a systematic analysis
11 of the literature regarding ovarian cancer and
12 specifically sort of evolving paradigms and research
13 in ovarian cancer?

14 A. Yes. I'm aware of that recent monograph and the
15 group that put it together to do that investigation by
16 CDC and Institute of Medicine.

17 MS. BROWN: Your Honor, I'm not sure where
18 this is. Can you direct me to the reliance list where
19 it is?

20 MS. O'DELL: Your Honor, it specifically
21 relates to an Institute of Medicine report that was
22 published this year, and Dr. Clarke-Pearson saw it
23 before, shortly after his deposition, actually. It
24 was published recently. It was not a part of his
25 reliance materials. But Ms. Brown, in suggesting that

1 talcum powder is not a risk factor recognized by the
2 CDC, is really not accurate. The CDC commissioned a
3 report by the Institute of Medicine. It's the
4 National Academy of Science issued a report called
5 "Ovarian Cancers Evolving Paradigms in Research and
6 Care," and they concluded that talcum powder and
7 asbestos are inflammatory risk factors of ovarian
8 cancer. I feel like that -- putting up that website,
9 suggesting they don't consider talcum powder, that
10 they don't consider talcum powder as a risk factor,
11 opened the door for us to show in fact they did.

12 MS. BROWN: Your Honor, I object, of course.
13 This is the first time I'm hearing of this document.
14 It was not included, obviously, in advance. It is not
15 included as part of the report. It's not included as
16 materials relied on. It's not included on a
17 supplemental reliance list and does not form the basis
18 of his opinion.

19 To the extent that counsel intended to use it,
20 we did not have the opportunity to review it, to have
21 our own experts comment on it. I literally have no
22 idea what it is and it was completely not disclosed.

23 THE COURT: Do you have it at counsel table?

24 MS. BROWN: I don't.

25 MS. O'DELL: She does. It's PSC

1717

1 Clarke-Pearson 3. We discussed it this morning. I
2 admitted it was not on his reliance list. It was an
3 oversight. I agreed not to use it. And then she put
4 into play, the CDC. It would be unfair to leave the
5 record with the suggestion that they don't consider
6 talcum powder a risk factor when I believe that's not
7 accurate.

8 THE COURT: Can I have a copy and see what
9 that looks like?

10 MS. O'DELL: It's in your binder, Judge, I
11 believe.

12 THE COURT: Let me take a quick look at what
13 this is.

14 MS. O'DELL: Your Honor, you will see it's the
15 National Academy of Sciences. I did bring the book,
16 your Honor. I got copies so counsel can have one,
17 too. If you want to see the book, I'm happy to hand
18 that up as well.

19 THE COURT: This was published when? It says
20 "Copyright 2016"?

21 MS. O'DELL: That's correct.

22 THE COURT: I want to understand what the
23 connection between this and the CDC is.

24 MS. O'DELL: Let me turn to the right page.
25 If you'll turn to page IX in the beginning,

1 this Congressional mandated report sponsored by the
2 Centers for Disease Control assesses the state of
3 research on ovarian cancer from multiple perspectives
4 and by multiple disciplines. So it's a CDC-sponsored
5 document or book.

6 MS. BROWN: Your Honor, it is not at all a
7 proper response to the current CDC position as
8 available on their website right now for what are the
9 risk factors for ovarian cancer. The proper redirect
10 on an exhibit like this is a page from the current CDC
11 website that says something else.

12 This, instead, is an older article by a
13 different organization that was never disclosed, and
14 no one has ever given an opinion about it, and it is
15 also about 30 to 40 pages. So I would object as not
16 properly in response to this at all, but, rather, an
17 attempt to backdoor in an undisclosed exhibit that
18 counsel gave me her word this morning it would not be
19 used with Dr. Clarke-Pearson.

20 MS. O'DELL: I didn't use it on direct, your
21 Honor. This is a page of the website. What you have
22 in front of you is a thorough systematic review of the
23 scientific evidence, and it's conducted in association
24 with the National Academies of Science, an
25 organization, I believe, if I remember correctly,

1 Dr. Neel said he wanted to be a part of at some point
2 in his career.

3 It's authoritative. They have a section
4 called "Inflammatory Risk Factors." It occurs on page
5 110, and beginning in the paragraph it says: "Studies
6 of the inflammatory marker, c-reactive protein,
7 suggest a possible association between inflammation
8 and an increased risk of ovarian cancer," and I'll
9 skip the cites for ease. "Other specific inflammatory
10 factors have been associated with ovarian cancer. A
11 meta-analysis reported that exposure to asbestos was
12 associated with a 77 percent increased risk of ovarian
13 cancer mortality," citing Camargo and the
14 International Agency For Research on Cancer to
15 determine that there was sufficient evidence to
16 support a causal relationship between asbestos
17 exposure and ovarian cancer," citing Straif. "This
18 has led to studies of talc use which is chemically
19 similar to asbestos and can cause an inflammatory
20 response. The use of perineal talcum powder has been
21 associated with 20 to 30 percent increased risk of
22 ovarian cancer, although it has been shown to vary by
23 histologic subtypes," citing Cramer and Terry.

24 MS. BROWN: You have to finish that paragraph.

25 MS. O'DELL: I'll be happy to.

1720

1 "One analysis reported 9 percent lower ovarian
2 cancer risk with regular aspirin use with stronger
3 results among daily users. Trabert. However, most
4 cohort studies have not observed a similar reduction
5 risk. Brasky, Lacey, Murphy, Ni, Pinheiro, Prizment,
6 and Setiawan."

7 That's the end of the paragraph.

8 MS. BROWN: Your Honor, this is not in at all
9 -- first of all, it's just an undisclosed 30-page
10 article that counsel and I spoke about this morning,
11 that she said she could not find on any reliance list,
12 and, therefore, agreed it was not appropriate to use
13 with this witness.

14 And now she's attempting to get it in front of
15 your Honor and to use it with this witness to rely on
16 it. It's not in his report, not on materials used,
17 not on the supplement. It has nothing to do with the
18 CDC's web page about ovarian cancer. It's a totally
19 different organization and it's a full report we would
20 have to read, analyze, have our own folks take a look
21 at. It's too late at this point, your Honor.

22 THE COURT: The only thing I'll do at this
23 point is, I don't want to take testimony on the
24 article. I'll note that the CDC current website is
25 still not listing this on it, even though they would

1 have had the benefit of a report they allegedly
2 commissioned.

3 So I will let you put on the record there was
4 a report at an earlier time that did study this issue.
5 But we also know what the CDC cites. So we'll put
6 that out there, and we won't take questioning on it.

7 BY MS. O'DELL:

8 Q. Dr. Clarke-Pearson, since reviewing the totality
9 of the evidence and reaching your opinions in this
10 case, what steps have you taken to inform others about
11 your opinion that genital use of talcum powder can
12 cause ovarian cancer?

13 A. I wasn't given the opportunity to make this
14 point --

15 MS. BROWN: Your Honor, there was nothing
16 disclosed in his deposition or his report about
17 efforts to do anything other than speak to a friend.
18 If the testimony is going beyond that, I would object
19 to his opinion that was not disclosed.

20 MS. O'DELL: It's not an opinion. It's a
21 fact. It's what he's done. He's engaging in the
22 medical community. There was no duty for him to stop
23 activities following his deposition on February 4th of
24 this year, and so I think he testified to several
25 items that he was in the process -- several steps he

1 was in the process of taking, and that's what I'm
2 asking about.

3 MS. BROWN: Your Honor, we had no opportunity
4 to depose him on this. It's all brand new. At the
5 time of his deposition, he had not done anything. If
6 he is here today with new things he has done, it's not
7 only beyond the scope of direct but it's an
8 undisclosed opinion that we have not had the
9 opportunity to depose him on and get to the bottom of
10 and --

11 THE COURT: I don't think I'm getting
12 opinions. I guess what I am going to get is, because
13 I understand the questioning was certainly there was
14 substantial questioning, there was nothing he had done
15 prior to being approach by plaintiffs' counsel in this
16 area and had not formed any opinions that there was a
17 causal connection.

18 He then analyzed it, came up with his
19 opinions, and I'm taking what you want to get now, is
20 he being in some way proactive now to do something
21 about his opinions? That's not more opinion. If he
22 wants to tell me he's doing things now, I'll listen to
23 what he's doing. I think that's where we're going.

24 MS. O'DELL: Yes, that's exactly it.

25 THE COURT: Go ahead.

1 THE WITNESS: So I made communication with two
2 organizations. I have talked to Dr. Hal Lawrence, who
3 is the CEO of ACOG, who had that one brief statement
4 that was --

5 THE COURT: I don't want to hear what he may
6 have said to you. Only what you have done.

7 THE WITNESS: I told him that I was serving as
8 an expert in the plaintiffs' side, but that based on
9 my analysis of the data that I would advise and
10 suggest -- I can't tell ACOG what to do -- that they
11 should investigate this in the format I would expect
12 of the committee opinion that we were talking about
13 earlier today. Dr. Lawrence I think --

14 THE COURT: I don't want to hear about that.

15 THE WITNESS: I also talked to Dr. Laurel
16 Rice, who is the immediate past president of the
17 Society of Gynecologic Oncology, and, finally, with
18 regard to patient information, I said that the patient
19 intake sheet in our oncology clinic doesn't include
20 talc. We will be updating, when we finish getting rid
21 or using up the forms we currently use in our general
22 obstetrics and gynecology clinic at the University of
23 North Carolina, a question about talc use, just like
24 we have with regard to seatbelts and smoking and those
25 risk factors.

1 THE COURT: That last one was an appropriate
2 follow-up to what I asked because I asked what the
3 forms looked like generally outside of his department.

4 You may proceed.

5 BY MS. O'DELL:

6 Q. Counsel put a number of magnetic labels on the
7 board here representing organizations, and, in
8 particular, statements they may have made to date.

9 To your knowledge, Dr. Clarke-Pearson, has
10 ACOG at this point undertaken a systematic review of
11 the scientific literature in the same way that you
12 have to reach your opinions?

13 A. I do not believe they have. That's why I
14 brought this up to Dr. Lawrence.

15 Q. Would it also be true that the FDA, at least at
16 this point, has not published a systematic review of
17 the scientific literature to date and rendered an
18 opinion on this topic?

19 A. That's correct. The only thing I have seen is
20 this letter we talked about earlier.

21 Q. Would it be true that the Society of Gynecologic
22 Oncology have not undertaken a systematic review of
23 the body of literature to reach an opinion on this
24 subject?

25 A. That's true.

1 Q. In terms of a regulatory agency who has
2 undertaken a systematic review, would it be fair to
3 say that the only regulatory body that has reviewed
4 all of the evidence and published their views of the
5 science would be Health Canada?

6 A. Yes. Health Canada has done a Bradford Hill
7 analysis.

8 Q. And what was their conclusion?

9 A. Their conclusion is very similar to my
10 conclusion.

11 MS. O'DELL: That's all I have, your Honor.
12 Thank you.

13 MS. BROWN: May I have a few minutes?

14 THE COURT: Yes.

15
16 RECROSS-EXAMINATION
17 BY MS. BROWN:

18 Q. Doctor, I want to start where counsel left off,
19 which is the Health Canada report.

20 Now, at the time that you issued your opinions
21 in this case that talc causes ovarian cancer, you had
22 not seen the Health Canada draft risk assessment.
23 True?

24 A. I don't believe I had.

25 Q. And you understand that the approach that Health

1 Canada took was a precautionary approach to
2 decision-making that emphasizes the need to take
3 preventive action. Right?

4 A. I'm not exactly sure what that means. They did
5 an analysis, a Bradford Hill analysis based on a
6 meta-analysis. I'm not sure what the precautionary
7 portion that you mentioned exactly means.

8 Q. Do you recall answering some questions about
9 this in your deposition?

10 A. I don't.

11 Q. Why don't we just take a look, then, at your
12 testimony.

13 Do you recall agreeing that Health Canada may
14 have made recommendations that are purely
15 precautionary? Do you recall that?

16 A. I don't recall it, but if I said it in my
17 deposition, then it would be true.

18 Q. Why don't we take a quick look at your
19 deposition, page 297, lines 9 through 14.

20 You were asked some questions about the
21 precautionary approach. You were asked:

22 "QUESTION: You understand that Health Canada
23 may have made recommendations that are purely
24 precautionary. Is that right?

25 "ANSWER: That's what I've read, yes."

1 Correct?

2 A. I guess that's what I read, but I'm not sure, as
3 I just said, what that exactly means.

4 Q. Incidentally, Doctor, the Health Canada draft
5 assessment was given to you by plaintiffs' lawyers.

6 Correct?

7 A. Yes.

8 Q. One of the things that Health Canada in the risk
9 assessment, the draft risk assessment, that was
10 provided to you by counsel for the plaintiffs
11 concluded was that

12 "There is a lack of an available exposure
13 effect relationship in the human epidemiological
14 data." Correct?

15 A. That's what they say.

16 Q. This is its most recent up-to-date analysis of
17 the data, according to your testimony. Is that right?

18 A. I think, once again, looking at all the data is
19 important.

20 Q. Another document that you were given by
21 plaintiffs' lawyers, after forming your opinion that
22 talc causes ovarian cancer, is a meta-analysis.

23 Correct?

24 A. Which meta-analysis are you talking about?

25 Q. You were given a meta-analysis by Taher and

1 others by counsel for the plaintiffs after you had
2 issued your report in this case. Is that right?

3 A. Yes, that's true.

4 Q. You did not rely on the analysis by Taher and
5 others at the time that you issued your opinions.
6 Correct?

7 A. That's correct.

8 Q. You understand that the Taher meta-analysis has
9 not been peer-reviewed. Correct?

10 A. It has not been published. I don't know where
11 it is in the process.

12 Q. Hasn't been published, not available on any
13 journals' website. Right?

14 A. Not that I'm aware of.

15 Q. Did you undertake an analysis to figure out
16 whether any member of the public can access this Taher
17 meta-analysis?

18 A. I did not.

19 Q. Did you ask the plaintiffs' lawyers who gave you
20 this meta-analysis how they got it?

21 A. No.

22 Q. Have you been to a website that the plaintiffs'
23 lawyers maintain called "The Truth About Talc"?

24 A. No.

25 Q. Can we look at slide 36, please.

1 Do you know that although unpublished and
2 un-peer-reviewed, the Taher meta-analysis is available
3 on a website called "The Truth About Talc"? Did you
4 know that?

5 A. I didn't know about the website, so I don't know
6 anything about what was on that website.

7 Q. If we can go to the next slide from this
8 website, did you know that the sponsor of the website
9 that has access to an unpublished meta-analysis that
10 underlies Health Canada is the Beasley Allen law firm?

11 A. Well, because I didn't know about the website, I
12 didn't know anything more -- I don't know anything
13 about the website.

14 Q. And in describing themselves as the sponsors of
15 The Truth About Talc website, that has the Taher
16 unpublished and un-peer-reviewed meta-analysis they
17 state:

18 "We have the experience and resources to
19 battle the corporate giant."

20 Have you seen that before?

21 A. I have not seen that before either.

22 Q. You know who Doctor Judy Wolf is. Correct?

23 A. I did.

24 Q. She is also an MDL gynecology oncologist expert
25 like yourself. Correct?

1 A. That's what I understand.

2 Q. And in preparing for your deposition in this
3 case, one of the things you did was review Dr. Wolf's
4 own deposition. Right?

5 A. I was given that opportunity, yes.

6 Q. Did you also review -- if we can go to the next
7 slide -- any of the 16 videos that Dr. Wolf has since
8 created for The Truth About Talc web page?

9 A. I have not seen any of those videos and was not
10 aware of them.

11 Q. So you are not then familiar with Dr. Wolf, an
12 MDL expert's video about addressing the skeptics in
13 the medical community?

14 A. I don't know what that is about, no.

15 Q. Did the plaintiffs' lawyers, in giving you the
16 Health Canada assessments and the Taher assessments,
17 did they give you a PowerPoint that was also
18 commissioned by Health Canada?

19 A. No.

20 Q. I want to take a look at that. It's
21 Exhibit 537. It would be in your binder,
22 Dr. Clarke-Pearson, at 537.

23 Now, do you know that Dr. Krewski did --

24 MS. O'DELL: Your Honor, she stated this was
25 commissioned by Health Canada. I don't know if she

1 intended to say that.

2 MS. BROWN: I'll go to the end to orient us.

3 Q. Do you see Dr. Krewski's name on this
4 PowerPoint? You have never seen this PowerPoint
5 before?

6 A. I have not seen the PowerPoint.

7 Q. Do you see that Dr. Krewski is the author of
8 this Population Health Risk Assessment?

9 A. Yes.

10 Q. And are you aware that he is also the lead
11 author on the Taher article that you were provided
12 with after your deposition?

13 A. I was not aware of that, no.

14 Q. Did you -- and just to follow up on counsel's
15 point, do you see this PowerPoint case:

16 "The work was conducted under a contract with
17 Health Canada and Risk Sciences International to
18 independently evaluate the association between talc
19 and ovarian cancer."

20 Were you aware of this funding source for this
21 PowerPoint?

22 A. No. I wasn't aware of the PowerPoint.

23 Q. I want to direct your attention to page 30 of
24 the PowerPoint that plaintiffs' counsel produced to us
25 a couple of weeks ago called "Cancer Classification."

1 Do you see that, Doctor?

2 A. I do.

3 Q. At the top is the IARC's 2010 review. Right?

4 A. Yes.

5 Q. And their conclusion that "The epidemiological
6 studies taken together provide limited evidence of an
7 association between perineal use of talc-based body
8 powder and an increased risk for ovarian cancer."

9 Correct?

10 A. That's what that says.

11 Q. Do you see the conclusion of this review which
12 was done for a contract with Health Canada concluding
13 that "based on this review, the criteria for
14 classification is a Group 3 A possibly carcinogenic to
15 humans." Do you see that?

16 A. Yes.

17 Q. And the information in the box, that "data from
18 epidemiological studies indicate an association
19 between exposure and human cancer but alternative
20 explanations such as chance, bias, or confounding
21 cannot be excluded." Do you see that?

22 A. Yes.

23 Q. Counsel for plaintiffs did not provide you with
24 this PowerPoint that they had by the author of Taher
25 done as a funding contract from Health Canada.

1 Correct?

2 A. Correct.

3 Q. And so you have not had the opportunity before
4 coming in here to discuss Health Canada to look into
5 what a Group 3 A possible carcinogen means under the
6 Canadian regulatory regime. Correct?

7 A. I don't know anything about it.

8 Q. As far as you know, the Health Canada report is
9 a draft assessment. Correct?

10 A. Yes.

11 Q. And whether or not and how, if at all, this
12 classification plays into Health Canada's final
13 classification is not something you know about.

14 Correct?

15 A. I do not.

16 Q. You have not had the opportunity to look through
17 this PowerPoint and see what the actual findings of
18 one of the Taher's authors was, when he conducted the
19 risk assessment. Correct?

20 A. Correct.

21 Q. That would include not having the opportunity to
22 see what he had to say or what the group of folks
23 conducting this risk assessment had to say about
24 biological plausibility. Correct?

25 A. Is this a peer-reviewed publication?

1 MS. O'DELL: I object to the assertion the
2 complete group of authors for the Taher paper
3 contributed to this PowerPoint because that does not
4 appear to be the case.

5 THE COURT: I think it says Krewski.

6 MS. BROWN: I'll rephrase to make sure it's
7 the lead author of Taher.

8 Q. Dr. Krewski.

9 THE COURT: Okay.

10 Q. Having not been provided this PowerPoint
11 presentation that we received a couple of weeks ago,
12 you have not had a chance to read and interpret
13 Dr. Krewski's thoughts or conclusions as it relates to
14 biological plausibility. Correct?

15 A. I have not.

16 Q. Including "the specific mechanism and cascade of
17 molecular events by which talc might cause ovarian
18 cancer have not yet been elucidated." Correct?

19 A. That's what it says.

20 Q. You have not had a chance to look through this
21 PowerPoint or any of Dr. Krewski's findings in this
22 risk assessment that was done pursuant to a contract
23 with Health Canada. Correct?

24 A. I have not. That's correct.

25 Q. You were asked some questions and you were shown

1 some epidemiology studies that suggested that it was
2 possible or even plausible for particles of talc to
3 migrate to the ovaries. Do you recall those
4 questions?

5 A. Yes.

6 Q. And you said that in fact supported your belief
7 that migration is possible. Correct?

8 A. I think it's very possible.

9 Q. And we spoke earlier today, though, about the
10 conclusions from the authors of the Penninkilampi
11 meta-analysis from 2018, the most recent one we have,
12 that "the possible mechanism by which genital talc is
13 associated with an increased risk of ovarian cancer
14 hence remains unclear."

15 Do you remember our discussion about that?

16 A. I remember we discussed that. I don't remember
17 exactly what we said.

18 Q. My question is: What methodology do you employ
19 to reject the conclusions from the Penninkilampi paper
20 that a mechanism remains unclear but to accept
21 conclusions from other epidemiology studies that
22 migration is the root of exposure?

23 A. I think I tried to explain it to the Court
24 before. This is a discussion section in a
25 meta-analysis. The meta-analysis was not intended to

1 look at biological mechanisms, potential mechanisms to
2 determine whether there was migration or not, or
3 whether there was anything to do with chronic
4 inflammation or not. These are all part of a
5 discussion after the data has been presented where the
6 author is allowed to speculate and go on with his
7 opinion. So this is an opinion based on their
8 opinions. There is no reference there. But it is not
9 part of the data that's presented in this study.

10 Q. So there's a bunch of references here, right?

11 When they are talking about the fact that
12 NSAIDs have not consistently been associated with the
13 decreased risk of ovarian cancer, they have a bunch of
14 references, don't they?

15 A. Yes. I was talking about the last sentence you
16 were talking about, which isn't referenced.

17 Q. In support of their conclusion a mechanism
18 remains unclear, they provide a number of references;
19 do they not?

20 A. They provide four references.

21 Q. And so what I want to understand, what
22 methodology do you employ to reject this part of the
23 most recent meta-analysis by Penninkilampi, that a
24 mechanism remains unclear, but to accept similar
25 discussions in other papers about the ability of talc

1 to migrate?

2 A. The scientific evidence and the experiments that
3 show that other particles similar to talc can migrate
4 to the ovaries very quickly from placement in the
5 vagina is more scientific evidence than this opinion
6 in the discussion section.

7 Q. You discussed with counsel on that score,
8 Doctor, this Venter article. Do you remember that?

9 A. Yes.

10 Q. This is an article from 1979. Correct?

11 A. Right.

12 Q. Regarding radio tracers that were placed near a
13 woman's cervix. Correct?

14 A. Yes.

15 Q. You know the IARC working group reviewed this
16 article in connection with their monograph on talc?

17 A. I hope they did. I have to look at their
18 reference list.

19 Q. And when you do, I'll represent to you you'll
20 find that this is there, and you know that the IARC
21 working group concluded, having, nonetheless, reviewed
22 this 1979 study you discussed with counsel, that they
23 concluded that the evidence of migration in a normal
24 woman is weak. Right?

25 A. Yes. We went through all that, and they talked

1 about something about the function of the genital
2 tract in those women undergoing surgery, which I don't
3 understand. There is other evidence that talc is
4 embedded in the ovary. So it gets there somehow. I
5 think the most plausible mechanism is for it to
6 migrate up the vagina and to the ovary and be embedded
7 in the ovary.

8 Q. And the 1970 article is one on which you rely
9 for that that opinion. Correct?

10 A. The radioactive article?

11 Q. Correct.

12 A. That's one of others.

13 Q. You spoke to counsel about some of your prior
14 publications that do not list talc as a risk factor
15 for ovarian cancer. Do you remember that?

16 A. Talking to you?

17 Q. I'm sorry, to counsel for plaintiffs, Ms. O'Dell
18 -- let me reorient you.

19 You spoke, when Ms. O'Dell came up to ask you
20 some more questions, she pointed out you only listed
21 certain risk factors and not others in certain
22 publications. Do you remember that?

23 A. In that review article regarding ovarian cancer
24 screening in the New England Journal 2009.

25 Q. I think I heard you say that you didn't risk any

1 of the inflammatory risk factors. Is that right?

2 A. Yes.

3 Q. In 2011, though, remember we spoke about this,
4 Pathways to Progress document earlier this morning?

5 A. Yes.

6 Q. You, again, had an opportunity to list them --

7 A. Can I explain -- I was the immediate past
8 president of the Society of Gynecologic Oncology. I
9 didn't write this.

10 Q. But before you signed your name on the cover
11 page that was going to go on top of this report, you
12 certainly read it. Right?

13 A. Yes.

14 Q. And this includes a discussion about risk
15 factors that includes family history. Right?

16 A. Yes.

17 Q. And it includes one of the potentially
18 inflammatory risk factors, obesity. Right?

19 A. Yes.

20 Q. It does not include talcum powder?

21 A. No.

22 Q. What's the relative risk for obesity and ovarian
23 cancer?

24 A. I don't know that answer.

25 Q. Do you consider obesity to be a recognized risk

1 factor for ovarian cancer?

2 A. It's on the list of recognized risk factors,
3 yes.

4 Q. You spoke to counsel about the NCI PDQ. Do you
5 recall that?

6 A. Yes.

7 Q. I think you had some concerns that the folks
8 doing that review were not doing a proper job doing
9 the up-to-date evidence. Correct?

10 A. Yes.

11 Q. What is the basis for that opinion?

12 A. The basis of that opinion was, as we talked
13 about a moment ago in redirect, about five papers that
14 were cited, and I think you pointed out to me this
15 morning or sometime today, that that PDQ is published
16 within the last year.

17 Q. The PDQ itself provides a reader with some
18 information about how frequently and the process by
19 which the authors update this. Did you know that?

20 A. No, I didn't see that.

21 Q. Let's take a look.

22 On page 17 of the PDQ that we have been
23 talking about that concludes there is inadequate
24 evidence for perineal talc to cause ovarian cancer,
25 we're provided with some information about how the

1 Board members keep up to date on the literature and
2 update these reviews, and what we learn is that this
3 summary is reviewed regularly and updated as necessary
4 by the PDQ screening and prevention editorial board.

5 Correct?

6 A. That's what that says. Apparently they are not
7 keeping up, though.

8 Q. Board members review recently-published articles
9 each month to determine whether an article should be
10 discussed at a meeting, be cited with text or replaced
11 or update an existing article that is already cited.

12 Correct?

13 A. Yes.

14 Q. You don't have any information about the
15 discussion or the review that went on by these board
16 members at their monthly meetings to review the
17 science that's contained in this PDQ?

18 A. I'm not privy to that conversation.

19 Q. (Reading.)

20 "Changes to the summaries are made through a
21 consensus process in which board members evaluate the
22 strength of the evidence in the published articles and
23 determine how the articles should be included in the
24 summary?"

25 Do you see that?

1 A. Yes.

2 Q. (Reading.)

3 "Any comment or questions about the summary
4 content should be submitted to cancer.gov through the
5 NCIs website."

6 Correct?

7 A. Yes.

8 Q. You told us a little bit earlier about some
9 activities you have undertaken since your deposition.
10 Have you emailed cancer.gov to complain about the
11 review of the board members on this NCI review?

12 A. I have not because I wasn't aware of this PDQ.

13 Q. Doctor, when I was talking to you about this
14 PowerPoint that you hadn't seen, I think counsel
15 raised an objection that it only reflected the views
16 of Dr. Krewski, the lead author, and Mr. Williams
17 reminds me that there is in fact a page of
18 contributors, and you see here that it includes the
19 first named author, Dr. Taher. Correct?

20 A. Yes.

21 Q. All of the authors listed on the Taher
22 meta-analysis. Right?

23 A. I believe so. I don't have the meta-analysis in
24 front of me.

25 MS. BROWN: I have no further questions, your

1 Honor. Thank you.

2 FURTHER REDIRECT EXAMINATION.

3 BY MS. O'DELL:

4 Q. Dr. Clarke-Pearson, the Health Canada
5 assessment, causal assessment, is it a comprehensive
6 review of the scientific evidence at this time?

7 A. As I've read it, yes, it is. It has a Bradford
8 Hill analysis.

9 Q. Does it have a Bradford Hill analysis? Is that
10 what you said?

11 A. Yes.

12 Q. And has it been peer-reviewed?

13 A. I don't know one way or the other on that topic.

14 Q. And in that assessment, did Health Canada
15 conclude that the connection between the genital use
16 of talcum powder and ovarian cancer is causal?

17 A. Yes.

18 Q. And is that your opinion?

19 A. Yes. That supports my opinion or is my opinion.

20 Q. And you were shown a number of slides from a
21 presentation by Mr. Krewski, Dr. Krewski, and this
22 presentation --

23 A. This is the PowerPoint I haven't seen?

24 Q. Yes. The PowerPoint from a presentation that
25 Dr. Krewski made in France.

1 Let me show you one of the slides you didn't
2 have a chance to see.

3 This is part of Dr. Krewski's presentation,
4 and he's walking through the Bradford Hill analysis
5 that was undertaken.

6 In bullet point No. 1, included in
7 Dr. Krewski's statistical significance presentation,
8 it says:

9 "Particles of talc appear to migrate into the
10 pelvis and ovarian tissue causing irritation and
11 inflammation. The presence of talc in the ovaries has
12 been documented."

13 A. That's what I was just saying based on the
14 literature I have read, not this.

15 Q. It goes on to say:

16 "The specific mechanisms and cascade of
17 molecular events by which talc might cause ovarian
18 cancer have not yet been elucidated.

19 Then it goes on to say:

20 "Chronic inflammatory response and alteration
21 in local immunogenicity are possible mechanisms of
22 action of talc as a risk factor for ovarian cancer."

23 Is that consistent with your opinion?

24 A. Yes.

25 Q. Ms. Brown showed you a picture of a website, The

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1 Truth About Talc. You haven't seen that website
2 before?

3 A. No.

4 Q. Did anything that Ms. Brown presented to you
5 during her opportunity to do recross, did that change
6 your opinions in this case?

7 | A. No, it does not.

8 MS. O'DELL: Thank you very much, your Honor.

9 THE COURT: Thank you. You may step down.

10 | We're done.

11 (Witness excused.)

12 (Court adjourned at 4:30 p.m.)

13 | // /

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C E R T I F I C A T E

5

6 PURSUANT TO TITLE 28, U.S.C., SECTION 753, THE
7 FOLLOWING TRANSCRIPT IS CERTIFIED TO BE AN ACCURATE
8 TRANSCRIPTION OF MY STENOGRAPHIC NOTES IN THE
9 ABOVE-ENTITLED MATTER.

10

11 S/Vincent Russoniello
12 Vincent Russoniello, CCR
13 Certificate No. 675

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